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AWARD NUMBER: DAMD17-01-1-0238

TITLE: Tailored Communication to Enhance Adaptation Across the Breast Cancer Spectrum

PRINCIPAL INVESTIGATOR: Suzanne M. Miller, Ph.D.

CONTRACTING ORGANIZATION: Fox Chase Cancer Center
Philadelphia, Pennsylvania 19111

REPORT DATE: October 2007

TYPE OF REPORT: Final

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
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REPORT DOCUMENTATION PAGE				Form Approved OMB No. 0704-0188	
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1. REPORT DATE (DD-MM-YYYY) 01-10-2007		2. REPORT TYPE Final		3. DATES COVERED (From - To) 1 Oct 2001 – 30 Sep 2007	
4. TITLE AND SUBTITLE Tailored Communication to Enhance Adaptation Across the Breast Cancer Spectrum				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER DAMD17-01-1-0238	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Suzanne M. Miller, Ph.D. E-Mail: Suzanne.Miller@fcc.edu				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Fox Chase Cancer Center Philadelphia, Pennsylvania 19111				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT The Behavioral Center of Excellence (BCE) in Breast Cancer was established to provide a comprehensive, multidisciplinary approach for studying the process of, and methods for facilitating, successful adaptation in the context of breast cancer risk, treatment, and recovery. The four ongoing studies are derived from and integrated by a unifying theoretical framework, and are supported by four care facilities (i.e., Administrative, Communication, Genetic Testing and Bioinformatics Core). The four projects are: 1) development of an intervention to promote utilization of breast cancer risk assessment programs and adherence to screening recommendations and underserved African-American women; 2) use of a "teachable moments and tailored communication materials to guide utilization of risk assessment and adherence to screening among daughters of diagnosed breast cancer patients 3) the development of psychological and physical adaptation among breast cancer patients at the completion of active treatments.; during the re-entry phase); 4) promotion of psychological adaptation among metastatic breast cancer patients. The overarching goal is to develop theoretically guided, tailored, and transportable breast cancer communications to enhance screening adherence, decision-making, and quality of life across the spectrum of disease (i.e., from risk through treatment to survivorship).					
15. SUBJECT TERMS Tailored Cancer Communications					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
U	U	U	UU	103	19b. TELEPHONE NUMBER (include area code)

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DOD Final Report, Project I
Understanding Breast Cancer Risk Assessment and Screening Behaviors Among the
Underserved

Suzanne M. Miller, Ph.D., Principal Investigator
Joanne S. Buzaglo, Ph.D., Co-Investigator
Andrea Barsevick, D.N.Sc., R.N., AOCN, Co-Investigator

October, 2007

Psychosocial and Behavioral Medicine Program
Division of Population Science
Fox Chase Cancer Center

INTRODUCTION

Breast cancer represents a serious health issue for African American women. Higher morbidity and mortality rates in this population may be due, in part, to lower uptake of breast cancer risk assessment and genetic counseling programs, as well as lower adherence to breast cancer screening recommendations (Miller & Champion, 1997). Yet, little information currently exists with respect to the psychosocial factors that facilitate participation in, and adherence to, available breast cancer risk assessment and screening programs. Further, there are no established intervention protocols to address the needs of this population. Guided by the research team's Cognitive-Social Health Information-Processing (C-SHIP) model, the overarching goal of Project 1 is to identify and assess barriers and facilitators to participation in breast cancer risk assessment and to adherence to breast cancer screening recommendations among African American women (Miller, 1995; Miller, 1996; Miller, Shoda, & Hurley, 1996; Miller, Fang, et al., 1999). These data will be used to develop and pilot test an intervention program to boost enrollment in breast cancer risk assessment programs and increase adherence to breast cancer screening guidelines among African American women.

The specific aims for Project 1 are as follows:

Aim 1: To develop a psychosocial assessment instrument, tailored to low-income African American FDRs of breast cancer patients, which assesses key psychosocial predictors of breast cancer surveillance behaviors (*Phase 1*).

Aim 2: To evaluate the psychometric nature of this questionnaire and to identify key longitudinal predictors (e.g., fatalism, attentional style) of participation in breast cancer risk assessment and of adherence to breast cancer screening recommendations (*Phase 2*).

Aim 3: To examine the feasibility and short-term impact of a cognitive-social intervention that is designed from Phase 1 and 2 data (*Phase 3*). Feasibility variables include number of recruitment calls needed, recruitment and attrition rates, level of satisfaction with the intervention, and degree to which women would recommend the program to others. Impact variables will include intention to pursue breast cancer risk assessment programs and adherence to breast cancer screening guidelines.

In Phase 1, we conducted seven focus groups with African American FDRs of breast cancer patients ($N = 27$). The participants were low-income, African American female FDRs of breast cancer patients/survivors (mean age 58.9 years). Participants were recruited from the tumor registry at Temple University Hospital (8), a support group at Temple University Hospital (7), and a community organization (12). Our goal was to develop a psychosocial assessment of barriers and facilitators of participation in risk assessment programs and adherence to screening guidelines. We expected that low monitoring as well as a pattern characterized by low levels of knowledge about genetic risk and assessment programs, inaccurate risk perceptions, high fatalistic beliefs, low pros and high cons about risk assessment, and extremely high levels of emotional distress would emerge as important correlates of program interest and screening adherence.

Phase 2 is a longitudinal study with African American FDRs of breast cancer patients to evaluate the psychometric nature of this instrument and to identify prospective psychosocial predictors of intention/readiness to pursue breast cancer risk assessment and screening adherence. We hypothesize that high monitoring, as well as greater knowledge, higher risk perceptions, lower fatalism, higher pros and lower cons, and moderate levels of emotional distress will predict greater readiness to pursue risk assessment and higher levels of screening adherence.

In Phase 3, we planned to examine the feasibility and impact of an intervention for African American FDRs of breast cancer patients ($N = 30$) on interest in breast cancer risk assessment and screening adherence; however, we were unable to execute this Phase due to recruitment difficulties in Phase 2.

Study findings will have applicability to enhancing current cancer prevention and control initiatives with underserved populations. This study will: 1) provide a theory-guided instrument for identifying women less likely to pursue risk assessment and adhere with screening guidelines; 2) identify a feasible, evidence-based approach to motivating breast cancer screening and participation in risk assessment programs among traditionally underserved women; and 3) provide information concerning the need for the simultaneous targeting and tailoring of interventions to promote decision-making about breast cancer assessment and adherence to surveillance behaviors. Overall, this study will provide important data for implementing breast cancer health-promotion interventions among underserved women on a broader scale.

BODY

The goal was to accomplish Task 1 through Task 6 as outlined in our Statement of Work. Below, we specify the tasks accomplished in the context of this project 1. In addition, we have provided estimates of time that it took to complete these tasks.

Task 1 (Months 1-6):

To refine a psychosocial familial risk questionnaire, tailored to low-income African American FDRs of breast cancer patients, that assesses key psychosocial correlates of interest in breast cancer risk assessment programs and adherence to breast cancer screening guidelines (*Phase 1*).

- | | |
|---|--------------|
| a. Submit Protocol to Institutional Review Boards | (Month 1) |
| b. Recruit Focus Group Participants for Phase 1 | (Months 2-3) |
| c. Conduct Focus Groups | (Month 4) |
| d. Analyze Focus Group Data | (Month 5) |
| e. Develop Assessment Instrument for Phase 2 | (Month 6) |

Task 2 (Months 7-72):

To evaluate the psychometric nature of the psychosocial familial risk questionnaire and identify key longitudinal predictors of participation in breast cancer risk assessment and of adherence to breast cancer screening recommendations among female African American FDRs of breast cancer patients ($N = 58$) (*Phase 2*).

- a. Submit Protocol to Institutional Review Boards (Month 7)
- b. Establish Recruitment Procedures/Staff Training for Phase 2 (Month 8)
- c. Recruit Participants, Conduct Longitudinal Study (Months 9-72)

Task 3 (Month 72):

To conduct interim analyses on all data collected from Phase 2 to ensure the validity and reliability of the data collection and in order to provide annual reports.

- a. Interim Statistical Analyses of Data Obtained from Phase 2 (Month 72)
- b. Annual Reports Prepared (Months 8-72)

Task 4 (Month 72):

To conduct analyses on Phase 2 data in order to identify the key predictors of interest in pursuing risk assessment and adherence to breast cancer screening recommendations. From these analyses, we will develop an intervention for this population to promote interest in risk assessment and adherence to breast cancer screening recommendations.

- a. Statistical Analyses of Phase 2 Data (Month 72)
- b. Develop Intervention from Phase 1 and 2 Data

Task 5:

To examine the feasibility and impact of an intervention designed using the data garnered from Phase 1 and 2 in terms of: recruitment and attrition rates, and intention to pursue breast cancer risk assessment programs and adherence to breast cancer screening guidelines.

- a. Submit Protocol to Institutional Review Boards
- b. Establish Recruitment Procedures/Staff Training for Phase 3
- c. Recruit Participants, Conduct Pilot Study

Task 6:

Analyze Phase 3 data and prepare formal reports for the granting agency as well as publication in academic journals and presentation at national scientific meetings.

- a. Analyze Phase 3 Data and Publicize Study Findings
- b. Prepare Final Report for Granting Agency (Month 72)

We have completed Phase 1 of the overall project (i.e., Task 1, a, b, c, d, and e). In Phase 1 of Project 1, we conducted focus groups with African American First-Degree Relatives (FDRs) of breast cancer patients ($N = 27$). Data from these focus groups have been used to develop a psychosocial assessment of barriers and facilitators of participation in risk assessment programs

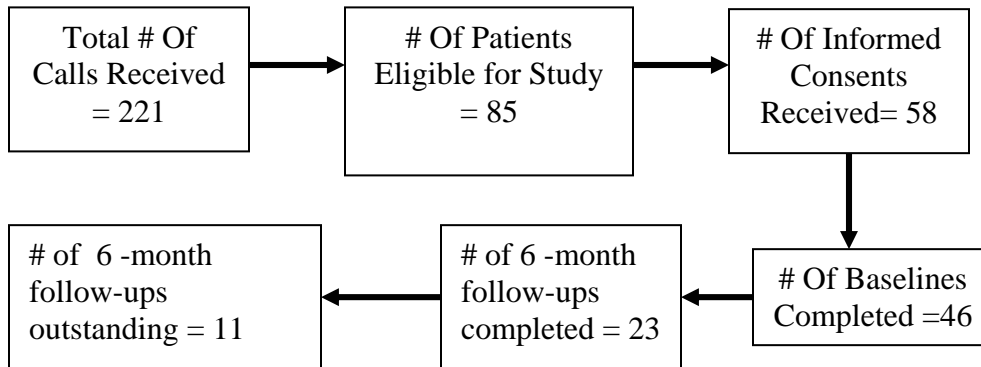
and adherence to screening guidelines. Further, guided by the Cognitive-Social Health Information Processing (C-SHIP) model, we applied a qualitative approach to explore patterns of cognitive-affective profiles of African-American women and their attitudes and beliefs about breast cancer risk and the options available to them. These qualitative data have been transcribed and analyzed to delineate and describe the individual's risk-related responses, in terms of their patterns of: risk perceptions, outcome efficacy of risk assessment procedures, risk-related distress, values related to the uptake of prevention and screening behaviors, and self-regulatory strategies to cope with the challenges associated with hereditary risk. These qualitative data will be used to enrich our understanding of the quantitative dataset by specifying more clearly the content of at-risk individuals' concerns. This is a unique data set in that it combines qualitative and quantitative approaches to the understanding and analysis of how minority women process complex information related to hereditary risk to breast and ovarian cancer, and the decisions and behaviors that ensue over time.

Phase 2 data collection began in the spring of 2004. When recruitment began, we were using Radio and Newspaper advertisements to recruit participants for the study. This method of recruitment yielded 47 participants who completed baseline assessments and 23 participants who completed 6-month follow-up assessments. During the course of year 5, in our attempts to increase recruitment, we submitted an amendment to recruit participants using invitation flyers distributed at various sites. Four new sites agreed to receive our flyers and strategically place them at meetings and gatherings where their members were most likely to congregate, in order to increase recruitment. The sites included two religious organizations; one breast cancer health information seminar and one breast cancer center that facilitates mentorship between breast cancer survivors and the newly diagnosed. The FCCC IRB and DOD approved these amendments. Flyers were distributed to these organizations, and an additional 11 participants completed baseline assessments in year 6. The 6-month follow-up assessments for the participants recruited in year 6 are pending completion in November and December of year 6 (2007). We will continue subject recruitment and retention for completion of Task 2c, Task 3a, and Task 4a with support from FCCC institutional funds.

With respect to Phase 3, based on our preliminary work in Project 1, we have developed an innovative approach to facilitate informed decision making about screening and prevention among culturally diverse underserved women attending the the Lynne Cohen Cancer Screening and Prevention Clinic for High Risk Women at Bellevue Hospital of the NYU Cancer Institute. Guided by the Cognitive-Social Health Information Processing model, the intervention is designed to facilitate understanding of personal risk, promote informed decision making about available screening and prevention options, and enhance adherence to follow-up recommendations among underserved minority women. The theory-guided telephone counseling intervention is delivered during women's first appointment at a breast cancer screening and prevention clinic with the objective to sustain participation over the long term for individuals at intermediate and high familial risk for breast cancer. We are currently in the process of conducting pilot work at the Lynne Cohen Clinic to support funding applications to evaluate the efficacy of this intervention.

As of September, 2005 Dr. Robert Schnoll is no longer at FCCC and Dr. Joanne Buzaglo has assumed his responsibilities on the project.

Figure 1: Summary of Recruitment Efforts (phase 2) through October 2007



A total of 58 participants consented to participate in the study. Of the 58 participants who consented, 46 participants have completed baseline assessments, and 23 participants have completed 6-month follow-up assessments. Participants' characteristics include:

Mean age = 45

Median age = 43.5

Education:

High School = 13

Some College or University = 21

Vocational or Technical school = 1

Graduate Degree = 11

Unknown = 12

KEY RESEARCH ACCOMPLISHMENTS

- Attended and participated in Center meetings.
- Completed recruitment for Phase 1 of project 1 (focus groups).
- Transcribed and analyzed focus group data
- For Phase 2 of Project 1, the total number of participants enrolled in the study is 58; out of which 46 completed baseline assessment and 23 completed the 6-month follow-up intervention. 11 Follow-up assessments are currently outstanding and due to be completed in November and December of 2007.
- Preliminary data analyses being conducted on Phase 2 data.

- A drafted telephone counseling intervention to facilitate informed decision making about screening and prevention among underserved women attending an inner-city screening and prevention clinic for high Risk women
- The Leadership Core applied for and received DOD approval for a second no-cost one-year extension for the time period from 2006-2007

REPORTABLE OUTCOMES AND BIBLIOGRAPHY OF PUBLICATIONS

Preliminary analysis has begun on the baseline data from Phase 2 of project 1. Compared to other women their age, 21% of participants report that they are at somewhat below to far below average risk for breast cancer, suggesting that there is a notable proportion of these women who underestimate their risk for breast cancer in spite of their familial history and elevated risk for developing the disease. Preliminary findings suggest that these women may have unrealistic expectations about screening and their likelihood of developing breast cancer. There is a gap in participants' risk-related knowledge. For example, 41% of participants reported that they believe after a clinical breast exam by a trained health care professional, they will know right away if something is wrong, suggesting that a substantial proportion of these women have unrealistic expectations about the reliability. This data clearly indicates that the majority of participants overestimate the reliability of a clinical breast exam.

There is a misconception that is held by women who participated in the study.

84% of this population believes that they are likely to develop breast cancer. This needs to be addressed through development and dissemination of a culturally sensitive intervention which increases health-related knowledge and awareness.

Aside from our recruitment activity, summarized in Figure 1, we do not have additional reportable outcomes at this point. We have just begun to analyze the data from Phase 2 of the project.

Phase 3 of the project was not initiated; however, we are currently in the process of re-submitting an NIH-R01. We have drafted an intervention for use with patients at New York University Hospital for this new project based on our experience and the data collected in Phase 1 and Phase 2 of the BCE project. Once all of the data from Phase 1 and Phase 2 has been analyzed, we plan to apply for R21 funding from the NIH in order to develop and test the feasibility of a readily transportable, culturally sensitive intervention designed to address the health concerns facing medically underserved women.

A number of paper presentations were made at the Department of Defense (DOD) Fourth Era of Hope Meeting, Philadelphia, PA, June, 2005. The paper focused on tailoring communication to enhance adaptation to breast cancer risk.

Presentations:

- Miller, S.M. Invited Speaker on Tailored Communication to Enhance Adaptation across the Breast Cancer Spectrum. Presented as part of Invited Symposium on Behavioral Centers of Excellence: Treating More Than the Tumor. The Department of Defense (DOD) Fourth Era of Hope Meeting, Philadelphia, PA, June, 2005.
- Miller, S.M., Chair of Invited Symposium on What Numbers Could Be: The Role of Numeracy in Understanding and Communicating Cancer Risk and Management Information Annual Meeting of the American Society of Preventive Oncology, Bethesda, MD, February, 2006.
- Miller, S.M., Chair, Invited Symposium and Roundtable Session on Health Disparities: Future Directions for Behavioral Medicine. Annual Meeting of the Society of Behavioral Medicine. San Francisco, CA. March, 2006.
- Miller, S.M., Co-Chair, Cancer SIG Lunch Meeting, Health Disparities: Future Directions for Behavioral Medicine. Annual Meeting of the Society of Behavioral Medicine, San Francisco, CA, March, 2006.

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CONCLUSION

Subject recruitment improved at FCCC due to continued identification and refinement of effective recruitment procedures. We have successfully completed Phase 1 of this project, namely the focus group interviews with 27 participants. Phase 2 recruitment is ongoing. We have begun some preliminary analysis, and final data analysis will be conducted once all participants have completed the study, projected for the end of 2007. This analysis will inform the development of multiple manuscripts.

REFERENCES

N/A

DOD Final Report, Project II
A Teachable Moment within the Family: From Concept to Community

Mary B. Daly, MD, Principal Investigator
Dr. Suzanne M. Miller, Ph.D., Co-Investigator
Samuel Litwin, Ph.D., Statistician

October, 2007

Psychosocial and Behavioral Medicine Program
Division of Population Science
Fox Chase Cancer Center

INTRODUCTION

Despite advances in cancer detection and treatment, breast cancer remains the most common cancer among women and accounts for a staggering number of lives lost per year. Knowledge about both the genetic and environmental causes of breast cancer is being translated into tailored screening protocols, chemoprevention approaches, and diet and lifestyle modifications, targeted to women at highest risk. First-degree relatives (FDRs) of breast cancer patients comprise a particularly appropriate group among whom to concentrate efforts to maximize risk reduction and early detection. Although a family history of breast cancer is a well-known risk factor, studies have shown that many women are unsure of their risk status and are often unaware of the cancer prevention strategies that may be appropriate for them. The diagnosis of breast cancer in a close relative may provide the ideal opportunity, a “teachable moment,” to reach at-risk family members to address their needs and concerns and make available risk assessment and counseling programs. The goals of the proposed study are to test a health communication message personalized to a set of demographic, clinical and psychosocial factors and timed to capitalize on the heightened awareness of breast cancer risk attendant to the recent diagnosis in an FDR. The project represents a partnership between a comprehensive cancer center (FCCC) and a series of community hospitals (FCCC Network/Partner affiliated sites) in an effort to enhance dissemination of state-of-the-art cancer prevention and control strategies to the community setting. Affected patients identify at-risk relatives at each site, and permission is sought to contact them by phone for participation in the study. Study participants are randomized to either a personalized message keyed to age, risk level, family history, screening behaviors and attention style, or to a general, non-personalized health message. Surveys are administered to adult daughters and sisters at two time points -- baseline and 12 months later -- in order to capture both newly formed intentions to seek cancer risk information and counseling, adopt lifestyle changes, and/or initiate appropriate surveillance regimens, and the actual action upon these intentions. The C-SHIP model of cognitive-affective processing of health threats is used as the theoretical framework for this study.

Aim 1: To develop and evaluate a theory-driven message tailored to a set of relevant variables including monitoring attentional style to enhance participation in FCCC’s Family Risk Assessment Program (FRAP). The hypotheses are that patients exposed to this tailored message will be more likely to 1) seek risk assessment and counseling through FRAP, and 2) adopt risk-reducing behaviors than those patients who receive a non-tailored risk message.

Aim 2: To examine the moderating effects of individual differences in educational level, relationship to the patient, and level of anxiety and cancer-related distress.

BODY

The focus in the project during the past year has been ongoing data collection to complete the 12-month follow up survey with participants at FCCC and VirtuaHealth. During the last year we have also focused on ongoing management of data as well as beginning some interim data analysis. As recruiting was completed in September 2006, all participants will complete the study by the end of 2007, allowing for final data analysis. The following is a description of the

research accomplishments associated with each Task as outlined in the approved Statement of Work.

Task 1: Study Start-up Phase

A. Communications core to create tailored, personalized messages for experimental intervention

The study staff and Communications Core developed a satisfaction survey which was administered to 55 Family Risk Assessment Program (FRAP) participants to assess their reasons for participating in the program. Facilitators and barriers to participating in FRAP were collected. These qualitative data were used to frame the development of the tailored messages to be used for the experimental intervention. The study team and Communications Core met on a regular basis to facilitate the development of the message library. Additionally, the study team met with the statistician to establish the randomization scheme. A cluster randomization was used such that multiple members of the same family will be randomized to either the experimental or control group.

B. Finalization of survey instruments

The baseline and 12 month follow up survey instruments were pilot tested to ensure usability when collecting complex information over the telephone. Study staff met with the Data Management Core on a regular basis to facilitate programming requirements enabling data capture and project timeline management.

C. Finalization of recruitment strategies

Recruitment strategies were finalized and corresponding recruitment tools were developed and approved by the DOD and FCCC IRB. These tools include: 1) a flyer to be distributed to breast cancer patients during clinic visits to describe the study, and 2) a participant brochure which describes the study and can be placed in patient waiting areas. Recruitment strategies were examined on an ongoing basis throughout the study at both FCCC and the Partner sites in the community. An amendment to the protocol was approved by the DOD and FCCC IRB to allow for first-degree relatives (FDRs) of breast cancer patients to contact the program directly (as opposed to being referred by their relative). This occurred in several situations during the study when the FDR read the brochure while accompanying their relative during treatment or follow-up visits and contacted the program directly. Additionally, an amendment was submitted and approved to change the inclusion criteria for “newly diagnosed” breast cancer patients from the original six to 12 months from date of diagnosis, to three to 12 months to expand the pool of potential participants. Study staff participated in various community events to recruit participants.

D. Training of study personnel

The Project Manager worked closely with the Research Assistant throughout the study on the use of the FCCC Health Information Management System to access patient records. This process was utilized to identify breast cancer patients to approach during their clinic visits at FCCC. Data entry and management plans were refined during the early stages of the study to ensure quality of study data. The FCCC Health Information Management System was changed during the course

of this study necessitating retraining and modifications to the procedures for identifying breast cancer patients to approach for this study.

Additionally, the Project Manager met several times with the study staff at four of the FCCC Partner hospitals who had expressed interest in collaborating with us. During these meetings, study procedures were reviewed and site logistics were discussed to ensure compliance with the protocol. Site-specific recruiting strategies were planned and the Project Manager assisted each of the sites in preparing submission to their respective IRBs. Meetings were also held with community physicians and their staff having the greatest potential to identify and refer appropriate patients for the study. The Project Manager continued working with the Partner sites to try and establish viable recruiting strategies in the face of very limited human resources at the site. All but one Partner site ultimately terminated the protocol due to lack of accrual. This was a function of staffing constraints at each site as well as limited staff ability to identify breast cancer patients in the local medical practices. VirtuaHealth did contribute several participants to the study.

The study team met on an ongoing basis to identify problems, develop support tools, and streamline the scheduling and implementation of the counseling sessions. A list of frequently asked questions (FAQs) and answers were developed with input from the counselors and this list evolved during sessions with study participants. Consultation with the Cancer Information Service management occurred in order to assess the training tools used by their health educators which were adapted when training staff for this study. Ongoing training of the health educators administering the intervention occurred throughout the study.

Most of **Task 2**, Conducting a prospective, randomized trial, has been completed. This task was subdivided into sub-tasks as follows:

A. Identification of FDRs

Patients were continuously identified through the FCCC clinical information system using the new 3-12 month inclusion criteria. Once eligible patients were identified, the study staff contacted them to set up a time to meet when they were scheduled to be at FCCC for a routine appointment. Once we briefly introduced the study to the patient over the phone and assessed preliminary interest and eligibility, a time and place to meet in person was arranged. A member of the study staff then met with the patient, explained the study, obtained informed consent and assisted the patient in completing the Relative Information form (RIF) to identify their eligible FDRs. In several cases FDRs contacted the study staff directly as a result of obtaining a brochure while accompanying their relative to a clinic appointment. This minimized the need to recruit the patient and complete the RIF first, streamlining the process of recruiting the FDR directly. As of September 1, 2006 identification of breast cancer patients and their FDRs was discontinued to allow for FDR's completion of the study during the final extension year of the grant.

B. Mailing of pre-call letter

Once the RIF was completed, precall letters were then mailed to the FDR along with the Relative Informed Consent and HIPAA forms to introduce the study. If the FDR did not call to decline

participation within a specified timeframe, the Informatics Core generated a contact log. This log flagged the date for the study staff to follow up on the precall letter with a phone call to assess the FDRs interest in participating in the study. Once we assessed eligibility and the FDR agreed to participate, the study staff reviewed the informed consent form with the participant and asked her to sign and return the informed consent and HIPAA authorization forms by mail.

C. Baseline telephone interview

Another phone call was scheduled for the baseline telephone interview at which time the baseline survey was completed over the telephone. This call only occurred once the signed forms were received back by the study staff. A photocopy of the signed consent and HIPAA forms were returned by mail to the FDR for their records. The survey took between 20-45 minutes to complete. The variability in time is mostly due to the size of the family and the accompanying family history information collected. Another call was scheduled within a few weeks of the baseline interview for the delivery of the counseling session.

D. Follow-up letter

Once the baseline interview and survey were completed, a follow up letter was generated by the Informatics Core and provided to the study staff. This letter confirmed the date and time for the upcoming telephone counseling session and was sent along with a small monetary reimbursement to the participant thanking her for her time and interest in participating. The baseline survey was entered into the database and the participant was randomized to either the experimental or control groups. A tailored script was generated for each woman in the experimental group based on several variables captured during the baseline telephone interview. An algorithm was developed with the Informatics Core to create the script for each participant in the tailored group. These variables included attention style, family history/risk level and compliance with breast cancer screening. For women in the control group, a general health information script was generated covering such topics as diet, dietary supplements and exercise. In advance of the counseling sessions, the Project Manager reviewed each script to ensure that the tailoring algorithm was correctly applied and that the text was personalized for the specific participant.

E. Delivery of experimental and control sessions

The experimental and control counseling sessions were completed by two Health Educators trained to administer the intervention. The sessions took from 10-30 minutes and concluded with a description of the local Family Risk Assessment Program with contact information on how to enroll. Participants were given the opportunity to ask questions throughout the session and were provided with additional resources (e.g. NCI website, Cancer Information Service) by the counselor as appropriate to the individual situation.

F. Quality control tests performed on a randomized sample of sessions

Twenty-three counseling sessions were audiotaped with permission from the participant and the Project Manager reviewed these tapes to assess quality control of sessions. Sessions were delivered appropriately and the format of the scripts encouraged interaction between the participant and the counselor. The counselor noted participants' comments throughout the session and completed an evaluation form at the end of each session. The Project Manager

reviewed all evaluation forms and addressed any problems or questions that arose during the session.

G. Follow up print materials mailed to participants

Follow up print materials (i.e. fact sheets) were mailed to participants within two weeks after the completion of their counseling session. These materials were developed with the Communications Core to correspond to the tailoring variables utilized in the tailored intervention group. Additionally, a fact sheet was created to reinforce information disseminated to control group participants. Also included in this mailing was a brochure and invitation to enroll in the local FRAP for more in-depth counseling and education about their risk for developing breast cancer.

H. Informatics Core to complete data entry and management

The Informatics Core staff entered and managed data on an ongoing basis throughout the study. Study staff met with the Informatics Core on a regular basis to ensure that participant data were being captured and project timelines were being met. Several project management reports were developed to assist the Project Manager with tracking progress of the study. Each study event was recorded through use of a checklist and data entry process on an ongoing basis. The study staff entered study checklists which captured each study event as every participant completed it. Additionally, appointments for telephone sessions were scheduled and managed utilizing an MS Outlook calendar.

I. Conduct 12-month follow up phone call

The 12-month follow up survey is administered by telephone one year after participants complete their counseling session. The Informatics Core generates a call log after a participant has been in the study for 11 months, and study staff contacts participants to complete the follow up interview. The follow up interview takes approximately 30 minutes to complete over the telephone. Once this interview is completed, the participant has completed the study. This task is ongoing as there are several participants due to complete the follow up interview by the end of 2007.

As there are several follow up interviews remaining to be conducted, **Task 3** is still in process. However, the subtasks are as follows:

A. Statistical analyses of data obtained

We have conducted some preliminary data analysis including descriptive statistics to characterize the study population which can be found in the next section. These data were also utilized in preparation for various preventions (e.g. Era of Hope meeting) throughout the year.

B. Publicize Study findings

As the study is not yet completed, no findings have been published.

C. Prepare final report for granting agency

KEY RESEARCH ACCOMPLISHMENTS

- Over 520 potential participants contacted
- Obtained informed consent on 166 subjects
- Completed baseline interviews with 159 subjects
- Conducted telephone counseling sessions with 157 participants (randomized to interventions group N=83 or control group N=74)
- To date, completed 12-month follow up interviews on 132 participants

Participant characteristics include:

- Age: 42 (median) (range 25-77)
- Race: 143 White; 10 African American; 2 Asian, 1 unknown, 1 other
- Education level:
 - 2 -8 to 11 yrs
 - 36- High school or GED
 - 7-Vocational or Technical school
 - 50-Some College
 - 40-Bachelor
 - 14-Graduate
 - 7-Doctoral
 - 1-unknown
- Participant enrollment in Family Risk Assessment Program: 2 tailored intervention group participant and 4 control group participants
- Explored and refined new recruiting procedures for identifying eligible breast cancer patients and their first-degree relatives at FCCC and Partner hospitals
- Amended protocol inclusion criteria to change definition of “newly diagnosed breast cancer patients” to 3-12 months from diagnosis in an effort to increase our pool of potential participants.
- Successfully collaborated with one FCCC Partner site to identify eligible participants from that community
- Attended and participate in monthly Center meetings.

REPORTABLE OUTCOMES AND BIBLIOGRAPHY OF PUBLICATIONS

A poster presentation was made at the annual meeting of the American Public Health Association in November, 2002. The poster focused on the process of developing the tailored communication messages:

Ross, B.S. & Daly, M.B. Cancer—A Teachable Moment Within the Family: From Concept to Community. American Public Health Association Annual Meeting. Poster presentation. Philadelphia, PA. November, 2002.

CONCLUSION

Subject recruitment was successful at FCCC due to continued identification and refinement of effective recruitment procedures. We were able to successfully establish a referral relationship with one of our partner hospitals in the community which led to the accrual of several participants. Recruiting from the other Partner sites proved to be a challenge mainly due to lack of human resources available to identify potential participants from the disparate medical practices in those communities.

The intervention was routinely delivered with very high quality as evidenced by consistently positive evaluations completed by the Health Educator following each telephone counseling session. These evaluations were reviewed by the Project Manager on an ongoing basis and compared with the audiotape recordings to evaluate the success of the session. Evaluations explored the Health Educator's impressions of the counseling session and covered such topics as whether the participant: understood the information contained in the session; seemed satisfied with the amount of information provided; had prior knowledge of the information; and asked questions during the session. Additionally we asked three study evaluation questions of each participant during the 12-month follow up call. The questions included satisfaction with the information received; if the participant would recommend this type of study to other women like themselves; and whether the study met their expectations. Responses averaged between "somewhat" and "very" on the response scale for each question.

Close collaboration with the Informatics Core throughout the study enabled the development of a variety of project/data management tools which were invaluable to the study staff. These tools allowed for close monitoring of the progress of the study and are currently being utilized in preparation for final data analysis. We have begun some preliminary analysis, and final data analysis will be conducted once all participants have completed the study, projected for the end of 2007. This analysis will inform the development of multiple manuscripts.

REFERENCES

Manuscript preparation is under way and will be submitted for publication once all data are collected and analyzed. Two manuscripts are currently planned and topics include:

- 1) A collaborative manuscript with all four BCE projects to provide an overview and evaluation of the recruitment process across projects
- 2) Assessment of the efficacy of the intervention administered in A Teachable Moment Within the Family: From Concept to Community.

DOD Final Report, Project III
Facilitating Re-entry Following Treatment for Primary Breast Cancer

Suzanne M. Miller, Ph.D., Principal Investigator
Joanne S. Buzaglo, Ph.D., Co-Investigator
Andrea Barsevick, D.N.Sc., R.N., AOCN, Co-Investigator
Lori J. Goldstein, MD, Co-Investigator
Ramona Swaby, MD, Co-Investigator

October, 2007

Psychosocial and Behavioral Medicine Program
Division of Population Science
Fox Chase Cancer Center

INTRODUCTION

As screening and surveillance for breast cancer has increased and treatment improved, the number of survivors of primary breast cancer has increased substantially (ACS, 2000; Pandey et al., 2000). The 5-year relative survival rate for localized breast cancer has increased from 72% in the 1940s to 96% today (ACS, 2000). Further, 71% of women diagnosed with breast cancer survive 10 years, and 57% survive 15 years (ACS, 2000). As the number of cancer survivors has increased, so too has the concern for the psychosocial adaptation of cancer survivors (e.g., Andersen, 1994; Ganz et al., 1996; Ganz et al., 1998; Gotay & Muraoka, 1998; Kornblith, 1998; Kurtz, Wyatt, & Kurtz, 1995; Schag et al., 1993; Wyatt & Friedman, 1996; Weitzner et al., 1997). However, little research has focused on easing the transition of individuals with early stage breast cancer from active treatment to follow-up care, referred to as the re-entry phase; even less research has focused on how individual differences moderate the process of adjustment to the challenges of survivorship (see Andersen, 1994; Helgeson et al., 2000). Guided by the Cognitive-Social Health Information Processing model (Miller, Shoda, et al. 1996; Miller, Mischel, et al. 1996), the primary objective of the proposed study is to develop and evaluate a tailored Cognitive-Affective Processing (CAP) intervention to facilitate psychosocial adjustment at re-entry following adjuvant treatment for primary breast cancer (Miller, 1995; Miller, 1996; Miller, Shoda, & Hurley, 1996; Miller, Fang, et al., 1999).

The specific aims for Project 3 are as follows:

Aim 1: To develop and evaluate a theory-based, individually tailored Cognitive-Affective Processing (CAP) intervention to facilitate re-entry following adjuvant treatment for primary breast cancer.

Aim 2: To examine the moderating effects of individual differences in attentional style (i.e., high vs. low monitoring) on the impact of the proposed intervention.

To reach the primary objective of the proposed study, three focus groups were conducted during Phase I of the study (months 1-6) at the Fox Chase Cancer Center (FCCC). Eighteen women from the target population (early stage, primary breast cancer patients) participated in the focus groups. The goal of the focus groups was to facilitate the development and refinement of the CAP intervention and the measures. The first two focus groups were designed to explore and assess the challenges confronted by the study population during the transition from being an active patient in treatment to a breast cancer survivor, i.e., the 're-entry' phase. Specifically, focus group participants were asked to discuss their perceived risk, expectancies and beliefs, values and goals, emotions, and coping strategies regarding their transition into 'survivorship'. Specific areas targeted included their cognitive-affective responses to cancer recurrence, cessation of treatment, sexuality, body image, and personal relationships. This information was used to further refine the intervention and measures. The final focus group was designed to obtain final suggestions for the improvement of the intervention and the battery of measures.

During Phase II, women who had been diagnosed with Stage 0, I, or II breast cancer and were being treated at FCCC were contacted for participation. Potential participants were identified through the scheduling office at the Breast Cancer Evaluation Clinic at FCCC and were recruited

within a year of completion of their adjuvant treatment. After they had been given a description of the study, participants who met eligibility criteria and wished to participate were asked to sign a consent form. Consenting participants were randomized into either the intervention or control condition. All but one consenting participant received the intervention or control session during a post-adjuvant treatment telephone session. One participant opted to complete her intervention session in-person during a follow-up clinic visit. A booster session was given two-weeks post-initial counseling intervention or control session. All participants were assessed via mail at one, six and twelve months post-booster session. The health educator would contact the participant by phone to remind the participant to complete and return this follow-up data in the event that participants did not return the questionnaires by their due dates.

BODY

During Year 1, we completed Task one and initiated Task 2 as outlined in our Statement of Work. Task 1 involves coordinating with the Communications Core in the testing and subsequent refinement of the cognitive-affective intervention designed to facilitate “re-entry” into the post-treatment phase of breast cancer for early stage breast cancer patients. This was to be accomplished through the use of focus groups to test both the intervention and the measures, with the Communications Core leading the process.

The specific aims of **Task 1** were to:

- | | |
|--|--------------|
| a. Recruit Focus Group Participants for Phase I | (Month 1-2) |
| b. Conduct Focus Groups | (Months 2-3) |
| c. Analyze Focus Group Data | (Month 3-4) |
| d. Refine Interventions/Measures | (Month 4-5) |
| e. Conduct Focus Groups to Evaluate Refined Interventions/Measures | (Month 5) |
| f. Establish Recruitment Procedures/Staff Training | (Months 5-6) |

The responses from the three focus groups, in addition to comments and suggestions made by an external review committee, were used to refine the barriers intervention. While the intervention continues to address the cognitive-affective mediating units of participants, there is now a more refined assessment of the primary concerns and issues of breast cancer survivors as well as the barriers to re-entry, which will be thoroughly addressed in the intervention session, with particular attention given to focus group participants’ preferences for the timing of the delivery of the counseling intervention and the method by which the intervention will be delivered. Specifically, the intervention is delivered soon after the completion of adjuvant treatment with follow-up assessments conducted at the one-, six-, and twelve-month time points. The intervention draws heavily from the NCI publication, *Facing Forward*, and is consistent with its philosophy of taking an active role in recovery in combination with accepting changes that are beyond the patient’s control. Further, the intervention provides strategies for coping with barriers to the re-entry phase of recovery and participants receive additional resources for dealing with their concerns. Revisions to the originally approved protocol were approved by the FCCC IRB in May 2004.

Because the information obtained from three focus groups was adequate to modify the barriers intervention, an amendment was submitted to conduct a pilot study ($N=20$) in place of the fourth focus group. This modification was also approved in May 2004. The recruitment for the pilot study was initiated in January, 2005 in order to provide an evaluation of both the initial assessment and the revised intervention in terms of their thoroughness, applicability and feasibility. To enhance accrual rates for the study, recommendations were obtained from FCCC specialists (i.e., physicians, nurses, technicians) working with women with breast cancer towards the end of their treatment, in order to find more efficient ways to reach potential participants for the study. Based on the input received, the following amendments to the study protocol were submitted to the FCCC IRB/RRC and DOD IRB:

a. Amendment #5: Change to eligibility criteria

In an effort to enhance recruitment, we proposed to expand the study eligibility criteria to include women up to three months following their last adjuvant treatment appointment rather than 3-4 weeks post-treatment. The differences in the amount of time since completing treatment among participants will be taken into account in data analysis. Submitted to FCCC IRB/RRC on March 30th, 2005, and received approval on April 5th, 2005. Submitted to the DOD on April 7th, 2005, resubmitted on October 5, 2005 and received approval on November 16, 2005.

b. Amendment #6 regarding recruitment materials

In an effort to facilitate recruitment of participants two recruitment materials were created: a brochure and a physician card. The brochure, to be displayed in the Radiation Treatment, Chemotherapy and Outpatient Clinic at FCCC, targets potential participants and contains study's description and contact information. The physician card targets medical staff working with patients with breast cancer and contains eligibility criteria, study description and contact information. Amendment was submitted to FCCC IRB/RRC on May 31st, 2005, and was approved on May 26th, 2005. Amendment was submitted to the DOD on June 28th, 2005. Approval from the DOD was received on October 20th, 2005.

c. Amendment #7: Measure instruments: replacement and additions to the set of study measures

One study measurement "Health Protective Behaviors" will be replaced by "Behavioral Action Taken", a study specific measure designed to assess the extent to which patients engage in the actions recommended by "Facing Forward" book – a publication designed especially for breast cancer survivors by the National Cancer Institute. This author-constructed measure consists of five sections, each reflecting a chapter covered in Facing Forward, designed to assess the adoption of specific actions recommended in Facing Forward (i.e., using a follow-up guide to keep track of appointments, developing a plan to fight fatigue, using a pain diary to track pain levels). Patients are simply asked to report "Yes or No" with regard to engaging in each of the recommended actions. This measure will be administered at baseline and at all three follow-ups. The rationale for proposing the replacement of "Health Protective Behaviors" measure with "Behavioral Action Taken" measure is that: 1) The "Behavioral Action Taken" measure targets health

protective behaviors that participants in both control and experimental group have been informed about through the Facing Forward publication; 2) The “Behavioral Action Taken” measure has been design in such a way to assess engagement in health protective behavior before and after the intervention. Another minor change proposed regards “Cancer-Related Benefits” Scale. We omitted to list it in Table III, on page 17-18: Provisional Measures and Times of Administration. This measure is now included in Table III, and it is described in the body of the proposal. Amendment was submitted to FCCC IRB/RRC on August 9th, 2005 and approval was received on September 29, 2005. An amendment was submitted to the DOD on October 5th, 2005 and approval was received on November 2, 2005.

d. Amendment # 8: Delivery of the intervention over the phone

Given that the high patient refusal rate to participate in this study has been often justified by lack of time to come for an in-person counseling session, this amendment proposed to offer participants in the study the option to choose between an in-person counseling session or an over-the-phone counseling session. The counseling intervention can be appropriately delivered over-the-phone, since is an educational counseling session designed to be easily transportable. Amendment was submitted to FCCC IRB/RRC on August 9th, 2005 and approval was received on September 29, 2005. An amendment was submitted to the DOD on October 5th, 2005 and approval was received on November 2, 2005.

e. Amendment #9: Extending eligibility criteria

Given the difficulty of reaching patients once they have finished adjuvant therapy, this amendment proposes to modify study eligibility criteria as to be able to recruit breast cancer patients while undergoing adjuvant therapy and/or within one year of their end of treatment. Amendment submitted to FCCC IRB/RRC on August 9th, 2005 with approval received on September 29, 2005. An amendment was submitted to the DOD on October 5th, 2005 and approval was received on November 2, 2005.

f. Amendment #10: Extending eligibility criteria

Given the continued difficulty of recruiting patients once they have finished adjuvant therapy, this amendment modifies the exclusion criteria from the original exclusion of all patients with previous cancer diagnoses to only those patients who had experienced a previous diagnosis of breast cancer, DCIS or LCIS. The amendment was submitted to FCCC IRB/RRC on April 5, 2007, with approval received on April 17, 2007. An amendment was submitted to the DOD on May 14, 2007 and approval was received on September 6, 2007.

Task 2, which was to be initiated during year 1 and continued into year 3, involves conducting the revised randomized trial (N=300) comparing the Cognitive-Affective Preparation (CAP) protocol designed to address the barriers to “re-entry” into the post-treatment phase of breast cancer for early stage breast cancer patients. The CAP intervention will be compared with a General Health Information (GHI) control to equate for time and attention. The specific aspects of Task 2 are to:

- a. Recruit Participants, Randomize to Treatments, (Months 7-30)
Test Interventions
- b. Participants Eligible for Genetic Testing will be (Months 7-30)
Referred to the Genetic Susceptibility Testing
Laboratory Core

Task 2 was initiated upon completion of the pilot study in January, 2006. Eleven pilot participants completed the baseline assessment. Because no problems were discovered during the pilot study, we retained the 9 pilot participants who completed the two-week booster session for the ongoing main study and started recruitment for Task 2 in January 2006. Given the challenge of recruiting participants for the pilot study, as of September 2005, several strategies to enhance recruitment were developed as outlined above. Implementation of these strategies was delayed due to the complex IRB approval process from both FCCC and the DOD. Successfully recruited participants were randomized to either the CAP or the GHI condition and their respective interventions were implemented.

Our team attended several consultation meetings with the Informatics Core to initiate the database edifice, and to adjust it in accordance with modifications to the protocol. The Informatics Core designed and developed Project 3's (baseline) application. The follow-up database and data entry interface(s) plus analytic views were generated.

Including the pilot study, from January 2005 until September 2007, 826 patients were evaluated for eligibility and 163 eligible participants were approached. 76 participants gave verbal consent, 60 provided written consent, 50 completed the baseline survey, 44 completed the intervention, 39 completed the 2 week booster session, 33 completed the one month follow-up, 19 completed the 6 month follow-up, and 14 completed the 12 month follow-up.

Below is a demographic description of those women who have been successfully recruited, who have completed the Informed Consent and HIPAA, and who have been randomized to the CAP or GHI conditions. As many Baseline questionnaires have not yet been returned, unknown factors are over-represented. As follow-up of consented participants continues, these unknown factors will become known, more accurately reflecting the demographic of recruited participants. Once the missing data becomes available, we anticipate the demographic figures below to mirror the general demographic of FCCC patients in general.

- 60 breast cancer patients enrolled to date
 - 35 in General Health Information (GHI)
 - 25 in (CAP)
- Primarily Caucasian
 - 68% Caucasian, 1.8% African American, 3.3% More than one race, 25% unknown, 1.8% other
- Age
 - 20-29: 0%
 - 30-39: 6.6%
 - 40-49: 21.7%
 - 50-59: 26.7%

- 60-69: 13.3%
- 70-79: 6.7%
- 80-89: 0%
- Unknown: 25%
- Primarily well educated
 - <8 years: 0%
 - 8-11 years: 1.67%
 - High School graduation/G.E.D: 13.3%
 - Vocational/Tech school: 0%
 - Some college or University: 23.3%
 - Bachelor's degree: 13.3%
 - Graduate degree: 11.67%
 - Doctoral: 5%
 - Unknown: 31.67%

Most of **Task 2**, conducting the revised randomized trial (N=300) comparing the Cognitive-Affective Preparation (CAP) protocol designed to address the barriers to “re-entry” into the post-treatment phase of breast cancer for early stage breast cancer patients with a General Health Information (GHI) control to equate for time and attention., has been completed. This task was subdivided into sub-tasks as follows:

A. Identification of potentially eligible patients

Patients were continually identified through the FCCC clinical information system using the new 12 month post-treatment inclusion criteria. Once eligible patients were identified, the study staff contacted them to describe the study to them in detail, review the informed consent document, and assess their interest and eligibility.

B. Informed Consent and HIPAA authorization

Once the patient was contacted and verbal consent or other indication of interest in the study was assessed, the Informed Consent and HIPAA documents were sent to them in the mail with a welcome letter, instructions, and a postage-paid envelope in which to return signed copies of both. Participants were given approximately one week to return these documents before being contacted by study staff to remind them. All points of contact were documented and logged in central study databases in order to track and monitor successful and unsuccessful times and days to call.

C. Baseline data collection

Once Informed Consent and HIPAA authorization were received from the participant, the baseline assessment was mailed to them, along with a postage-paid envelope. Participants were generally given 2 week to return this packet of questionnaires before study staff began placing reminder calls to participants. Again, every call was documented in a central participant data base to track when best to reach them. Along with the baseline packet was mailed an instruction letter and a form on which they could indicate their preferred method of intervention, phone or in person,. If they chose phone, they also indicated a good date and time at which they could be reached for the initial intervention or control session. Participants were instructed to choose a

date and time that fell two weeks from when they completed their baseline questionnaire packet. This date and time was confirmed by phone by study staff.

D. Delivery of experimental (CAP) and control (GHI) sessions

The CAP intervention session was conducted at the agreed-upon time, usually 2 weeks following the completion of the baseline questionnaire. A research assistant would call the participant to confirm that this time was still amenable to the participant, and the research assistant would guide the participant through a series of questions and snippets of information relating to the participant's answers on the barriers assessment portion of the baseline questionnaire. Participants were encouraged to ask questions and expound on any issues they may have noted in their baseline questionnaires throughout the CAP intervention. The session would conclude with a brief introduction to the Life After Cancer Treatment book that was sent to all participants following this initial intervention. The research assistant would then schedule a 2-week follow-up with the participant to go over the issues discussed at the initial intervention, as well as how utile the participant found the Life After Cancer Treatment book. This 2-week follow-up would address the issues brought up in the initial intervention and any new issues that the participant wanted to discuss, as well as the participant's impression of the utility of the Life After Cancer Treatment book.

The GHI control session was conducted at the agreed-upon time, usually 2 weeks following the completion of the baseline questionnaire. Participants were introduced to the Life After Cancer Treatment book, with the research assistant walking them through the chapters, providing examples of what was covered in each chapter. At the end of this initial GHI control session, the research assistant would set up a 2-week follow up appointment with the participant, during which the research assistant would assess the utility of the Life After Cancer Treatment book with the participant. The participant would then be asked if she had any further questions or comments and the session was concluded.

E. Follow up materials mailed to participants

Follow up questionnaires were mailed to participants 1-, 6-, and 12-months after their 2-week follow-up intervention or control session. A research assistant would call the participant if their materials were not returned within a week of their due date until the materials were returned. A duplicate of the questionnaire would be sent in the event that the participant reported it never arriving or it having been lost.

H. Compensation

Participants were compensated \$20 for having completed both the initial CAP intervention or GHI control session, \$20 for completing the 1- and 6-month follow-up questionnaires, and a final \$20 for completing the 12-month follow-up questionnaires. Each check would be mailed along with a thank you letter. The final check was mailed with a final thank you letter, letting the participants know that this check marked the end of their participation in the breast cancer re-entry project.

Task 3 involves conducting data analyses on all data collected and presenting/publishing findings. However, due to delays in the revision and approval of the intervention as well as of the recruitment procedures, there is not enough data collected to complete this task. To allot for

the extra time that will be needed to collect additional data and complete task 3, we requested an additional no-cost extension to continue this study in 2007

- | | |
|---|----------------|
| a. In collaboration with the Informatics Core | (Months 31-42) |
| Statistical Analyses of Data Obtained | |
| b. Publicize Study Findings | (Months 43-48) |
| c. Prepare Final Report for Granting Agency | (Months 43-48) |

This additional no-cost extension was approved and received. Because of delays in recruitment due to above-mentioned amendment IRB procedures, this additional year allowed us to increase our recruitment numbers. Preliminary analyses are being performed on these additional numbers.

KEY RESEARCH ACCOMPLISHMENTS

- Continue to attend and participate in monthly Breast Cancer Care Team meetings
- Conducted meetings with FCCC Outpatient Clinic, Breast Cancer Clinic, and Ambulatory Care - Infusion Room staff (physicians, nurses, technicians) in order to get their input and support for increasing participation in the study.
- Developed recruitment materials (i.e. physician cards, in-clinic brochures) in order to better reach potential participants.
- Submitted revisions to the FCCC IRB regarding use of recruitment materials, and extension of eligibility criteria in order to increase study accrual. Submitted the FCCC IRB approved revisions to the DOD and Approval is pending.
- Revised the study measures based on the preliminary information from the pilot study. “Behavioral Action Taken” will replace the “Health Protective Behaviors” measure upon FCCC and DOD IRB approval. This is a study-specific measure designed to assess the extent to which patients engage in the actions recommended by “Facing Forward” book – a publication designed especially for breast cancer survivors by the National Cancer Institute.
- Submitted a new HIPPA authorization form using a new template developed by the FCCC IRB to DOD for approval.
- Data collection procedures were established with the Informatics Core to initiate the database edifice.
- 14 patients were recruited for and provided written consent for the pilot study. Pilot baseline data was collected for 11 participants. Of these 11 initial pilot participants, 10 participants completed the intervention, 9 completed the 2 week booster session, 6 completed the one month follow-up, 4 completed the six month follow-up, and 2

completed the 12 month follow-up. The pilot participants that completed the 2-week booster session were retained as participants in the ongoing study.

- Including the pilot study, 826 patients were evaluated for eligibility and 163 eligible participants were approached. 76 participants gave verbal consent, 60 provided written consent, 50 completed the baseline survey, 44 completed the intervention, 39 completed the 2 week booster session, 33 completed the one month follow-up, 19 completed the 6 month follow-up, and 14 completed the 12 month follow-up.
- Additional staff was trained in recruitment procedures so that recruitment calls could be made more often on different days of the week. Evening recruitment calls were also initiated for participants who could not be reached during business hours.
- Applied and received DOD approval for a second no-cost one-year extension.
- We have established a collaborative relationship with the Soroka breast health center at Ben Gurion University of the Negev, Israel. We are in the process of translating the intervention and assessment protocols developed for this study to be tested and evaluated in the context of a comprehensive community-based survivorship program in the Negev.
- Based on the research and experience acquired through this portion of the BCE project, we have been awarded a grant from the Lance Armstrong Foundation. This grant is intended to further assess and address the needs of survivors of cancer. The project will identify the needs of young adult cancer survivors (ages 18-40) residing within the Southeastern Pennsylvania (SEPA) region. Young adult cancer survivors represent an understudied and underserved subset of cancer survivors. The overarching goals of this project are to understand the unique constellation of needs of the target community, and to assess and address gaps in service delivery. This Community-Based Participatory Research (CBPR) program will enable us to establish an infrastructure to pursue future research and program planning efforts focused on this unique age group in SEPA that can be used as national model
- Two manuscripts are currently planned and topics include:
 - A collaborative manuscript with all four BCE projects to provide an overview and evaluation of the recruitment process across projects
 - A collaborative manuscript with the Communication Core to present findings from the qualitative analysis of the focus group interviews with respect to barriers to successful adaptation to the transition from breast cancer treatment to survivorship.

REPORTABLE OUTCOMES AND BIBLIOGRAPHY OF PUBLICATIONS

We are currently conducting preliminary analyses of the data provided in both Projects I and III. Results are forthcoming.

In addition, a number of presentations have been made including one at the Department of Defense (DOD) Fourth Era of Hope Meeting, Philadelphia, PA, June, 2005. Please see below.

- Miller, S.M. Invited Speaker on Tailored Communication to Enhance Adaptation across the Breast Cancer Spectrum. Presented as part of Invited Symposium on Behavioral Centers of Excellence: Treating More Than the Tumor. The Department of Defense (DOD) Fourth Era of Hope Meeting, Philadelphia, PA, June, 2005.
- Miller, S.M., Chair of Invited Symposium on What Numbers Could Be: The Role of Numeracy in Understanding and Communicating Cancer Risk and Management Information Annual Meeting of the American Society of Preventive Oncology, Bethesda, MD, February, 2006.
- Miller, S.M., Chair, Invited Symposium and Roundtable Session on Health Disparities: Future Directions for Behavioral Medicine. Annual Meeting of the Society of Behavioral Medicine. San Francisco, CA. March, 2006.
- Miller, S.M., Co-Chair, Cancer SIG Lunch Meeting, Health Disparities: Future Directions for Behavioral Medicine. Annual Meeting of the Society of Behavioral Medicine, San Francisco, CA, March, 2006.

Further, a number of relevant publications have been supported by the BCE. See below:

- Miller S.M. & Roussi, P. (2005). Genetic Testing for Breast and Ovarian Cancer: A Review of Psychological and Behavioral Outcomes. *Hellenic Journal of Psychology*, 2, 135-58.
- Vernon, S., Meissner, H.I., & Miller, S.M. (2006). The role of behavioral science in cancer prevention research: Planning the next steps in the collaborative process. *Cancer Epidemiology, Biomarkers, and Prevention*, 15, 413-15.
- Miller, S.M., McDaniel, S.H., Rolland, J.S., & Feetham, SL. (Eds.) (2006). *Individuals, Families, and the New Era of Genetics: Biopsychosocial Perspectives*. New York: Norton.
- Hiatt, R.A., Miller, S.M., & Vernon, S.W. (in press). Translational Research and Good Behavior. *Cancer Epidemiology, Biomarkers and Prevention*.
- Miller, S.M., Bowen, D.J., Croyle, R.T., & Rowland, J. (Eds.) (in press). *Handbook of Cancer Control and Behavioral Science: A Resource for Researchers, Practitioners, and Policy Makers*, Washington, DC: American Psychological Association.
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CONCLUSION

With the successful formation, execution, and completion of the three focus groups, task 1 study elements have been completed. Best practices in breast cancer re-entry were informed by the women of the focus groups, allowing the research team to formulate a relevant and significant intervention for this seminal period in breast cancer re-entry and survivorship. Task 2 elements, including recruitment of participants to the main study and implementation of both the CAP and GHI portions of the study, continues to date. Additional power analyses by FCCC statisticians have shown that a comparable effect can be found using a new N of 100, as compared to the initially projected N of 300. Part b of task 2, the referral of eligible project III participants to the Genetic Susceptibility Testing Lab Core, is a promising opportunity for future direction of the data collected. Based on their ongoing work, the Genetic Susceptibility Testing Lab Core is in optimal position to appropriately analyze BCE samples once they become available through Projects 2 and 3. Task 3 involved analyzing all collected data. Due to unforeseen setbacks in recruitment, our originally proposed N of 300 has been amended to N=100. Fox Chase Cancer Center statisticians have performed/formulated additional power analyses to allow us to reach power with this final N of 100, and we plan on continuing recruitment and follow-up until 100 participants are accrued and have completed the protocol, at which time final data analyses will be conducted and manuscript preparation will follow.

REFERENCES

N/A

DOD Final Report, Project IV
Communication Skills Versus a Supportive Therapy Intervention for Women with Metastatic
Breast Cancer

Dr. Sharon Manne, Ph.D., Principal Investigator
Dr. Karthik Devarajan, Ph.D., Statistician

Psycho-Oncology Program
Division of Population Science
Fox Chase Cancer Center

October, 2007

INTRODUCTION

Excluding skin cancers, breast cancer is the most common cancer diagnosed in American women. Recent advances in early detection and treatment have resulted in higher cure rates for breast cancer. Unfortunately, approximately 6% of breast cancer patients develop metastatic disease (stage IV). For the majority of women diagnosed with metastatic breast cancer, median survival is approximately 18 to 24 months with systemic chemotherapy. The overall five-year survival rate for women with stage IV breast cancer is 21.3%. Thus, although a cure is not achieved for most patients, treatment improvements have made it possible for women to survive for relatively long periods of time with stable disease. Consequently, symptom relief and improvement in quality of life are critical therapeutic goals for this population.

The specific aims for Project 4 were as follows:

Aim 1: To compare the effectiveness of a communication and support skills intervention versus a supportive therapy intervention on the quality of life of women with metastatic breast cancer.

Aim 2: To explore the effects of individual differences (e.g., ambivalence over emotional expression), treatment expectancies, social support and coping on the impact of the interventions.

This was a multi-site study, with prospective subjects being identified at the Fox Chase Cancer Center (FCCC), Cooper Health System Division of Hematology/Oncology, Temple Cancer Center, and Bryn Mawr Hospital (BMH) of the Main Line Health System. On-site physicians regularly provided the research assistant with a list of eligible patients who have given permission to be contacted for this study. Eligible participants were mailed a letter describing the study. Patients were approached and contacted in person by the Research Study Assistant during a clinic appointment, and the study was described in more detail. If the participant is interested in participating, informed consent was to be obtained at that time. After obtaining written informed consent, the pre-intervention assessment packet was administered.

The study design was a randomized clinical trial with two study conditions: 1) Communication and Support Skills intervention, 2) Supportive counseling intervention. Patients were assigned to one of these conditions after the initial packet has been completed. The intervention programs were administered in an individual format with six in-person sessions and one telephone follow-up. Assignment was stratified into groups having low or high baseline psychological distress as determined by the Beck Depression Inventory.

The goal of this study was to determine whether an intervention targeted to women with breast cancer can impact their psychological distress. We utilized a structured, CBT-oriented intervention that taught effective communication and support skills because this type of intervention was thought assist patients in obtaining support from their existing support networks (rather than from other patients). Prior studies have suggested that deficits in support from partners and a lack of open engagement with partners are particularly problematic for female, late stage patients and among metastatic breast cancer patients. We selected supportive psychotherapy as a comparison condition because this intervention will not provide skills, but provides emotional support. In addition, this condition provides a control for the non-specific

effects of therapy (therapeutic bond, treatment expectancies, time and attention spent on the patient). We examined the role of these non-specific factors in treatment outcome. We also will assess adherence to treatment protocol and treatment discrimination, which have been ignored in prior research. By focusing an individual difference variable (lack of support) that has been shown to predict a beneficial outcome for interventions, we may be more likely to elicit a response to treatment that has not been consistently found in prior studies of metastatic breast cancer patients.

BODY

Below are the specific tasks accomplished, as originally outlined in the Statement of Work, in the context of this Project 4. In addition, we have provided estimates of the amount of time it took to complete these tasks.

Task 1 (Months 1-5):

To refine the intervention manual for the support skills intervention and train psychotherapists in administration of both interventions.

- | | |
|--|--------------|
| a. Recruit Focus Group Participants | (Months 1-2) |
| b. Conduct Focus Groups | (Month 3) |
| c. Analyze Focus Group Data | (Month 4) |
| d. Train therapists in both conditions | (Month 5) |
| e. Prepare study questionnaires, recruitment materials, materials for therapists | (Month 5) |

Task 2 (Months 6-60).

- | | |
|---|---------------|
| a. Recruit participants | (Months 6-60) |
| b. Administer study questionnaires | (Months 6-60) |
| c. Conduct intervention sessions | (Months 4-60) |
| d. Regular therapist supervision meetings | (Months 4-60) |
| e. Enter study data | (Months 4-60) |
| f. Conduct follow-up assessments | (Months 4-60) |
| g. Treatment integrity checks | (Months 4-60) |

Based upon previous experience, Project 4 staff determined that focus groups would prove redundant to earlier work and experience conducted with this patient population. Therefore, in place of the focus groups (Task 1a, 1b and 1c) staff regularly met with the study interventionists in order to develop and tailor the intervention material. The training of project therapists (1d) was completed as scheduled. Though questionnaires and therapist materials were completed as scheduled (1e), there was some delay and in the production of recruitment materials due to nature of the multi-site IRB approval process. Materials have included posters, letters (signature stamped by prospective participant's oncologists), pamphlets, and stickers to be attached to eligible patients medical charts. Currently all recruitment materials have been approved.

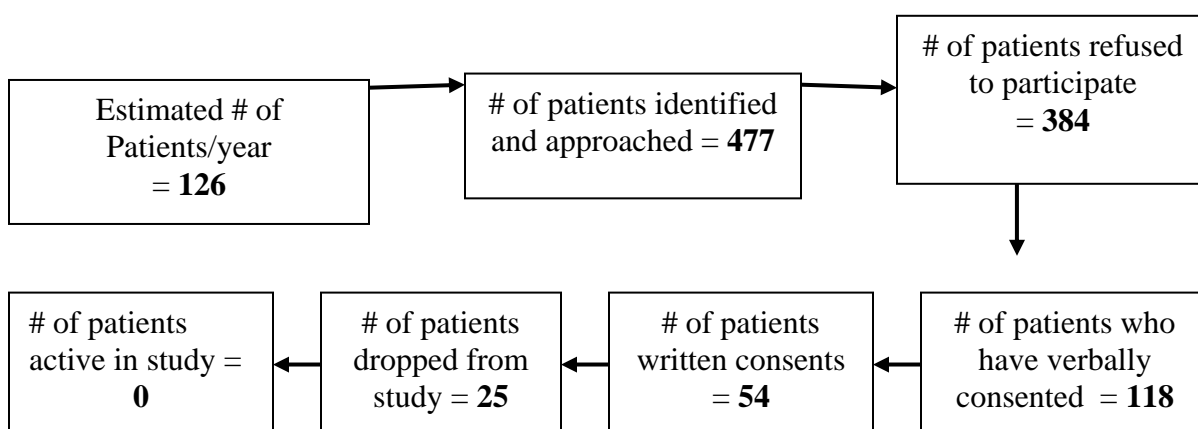
There was approximately a 4-month delay in start-up due to multiple protocol amendments and their respective DoD and multi-site IRB approval requirements. Study questionnaires and conducting of intervention sessions (2b, 2c) commenced after the start-up delays, and has kept pace with recruitment. The PI and Project Manager conducted regular therapist supervision (2d) with the interventionists throughout the study. Data entry (2e) was completed with recruitment and intervention sessions. Project 4 staff worked closely with the Informatics Core in order to develop data entry protocols, computerized data entry form screens, and a system which allows Project 4 staff to be automatically notified when different questionnaire elements are due to be sent to patients. Follow-up assessments and treatment integrity checks (2f, 2g) were conducted on a regular basis. Intervention sessions were audio taped for treatment integrity-tracking purposes.

Despite efforts to increase enrollment by approaching patients in-person and increasing awareness of our project among the oncologists treating patients at Fox Chase Cancer Center, the recruitment figures were lower than originally anticipated. Low recruitment figures continue to stem from two primary causes; 1) we have identified fewer eligible individuals than previously estimated, and 2) we have experienced a higher refusal rate than anticipated. Below, in Figure 1, we summarize our recruitment efforts. Our sample size at this point is 53. 29 women were assigned to the Communication and Support skills condition and 24 women were assigned to the supportive condition. Of the 29 women assigned to the Communication and Support skills condition, twenty have completed all six sessions and nine have dropped out of study. Of the 24 assigned to the Supportive counseling condition, seventeen women have completed all 6 sessions and seven have dropped out. Thirty-five of our 53 participants have completed the first follow up and twenty-eight have completed the second follow up survey. Participant characteristics include:

- 54 breast cancer patients enrolled to date
 - 30 in Communication and Support Skills Counseling
 - 24 in Supportive Counseling
- Primarily Caucasian
 - 87% Caucasian, 11% African American, 0% Asian, 0% Other, 0% One Race, 2% Unknown
- Ethnicity
 - 2% Hispanic/Latino, 98% Unknown
- Age
 - 20-29: 0%
 - 30-39: 6%
 - 40-49: 26%
 - 50-59: 24%
 - 60-69: 30%
 - 70-79: 13%
 - 80-89: 2%
 - Unknown : 0%
- Primarily well-educated
 - 0 - 4 years of school - 1.9%
 - 5 - 8 years of school - 1.9%

- Finished high school - 33.3%
- 1 - 3 years of college - 20.4%
- 4 years of college - 7.4%
- Trade of Business School - 11.1%
- Some Graduate School - 11.1%
- Graduate Degree - 13%

Figure 1: Summary of Recruitment Efforts through 9-2007



In terms of other study tasks, all session audiotapes were coded for integrity by Jeanne Schueller, the previous project manager. All study data has been entered to date, and supervision of study therapists has been completed. Feedback for the therapists was given from Sharon Manne to each therapist as well as accomplished by in person supervision meetings every 3-4 months.

KEY RESEARCH ACCOMPLISHMENTS

- Attend and participate in monthly Center meetings.
- Completed recruiting patients, both at FCCC and satellite sites.
- Completed administering the experimental interventions.
- Further development and tailoring of the interventions.
- Trained the interventionists.
- Further development of the recruitment procedures.
- Finalization of study assessment instruments.
- Utilized Informatics Core to develop and maintain data collection and management procedures.

REPORTABLE OUTCOMES AND BIBLIOGRAPHY OF PUBLICATIONS

Aside from our recruitment activity, summarized in Figure 1, we do not have additional reportable outcomes at this point. We have just begun data analyses.

CONCLUSION

Task 1 study elements have been completed. Task 2 elements, including recruitment, intervention, treatment integrity and supervision, and data collection and entry are completed. We made significant efforts to boost enrollment by adding a number of local hospitals to our study as well as by increasing awareness of our project among the oncologists treating patients at Fox Chase Cancer Center. In addition, we recruited patients through in-person approaches when they came to the clinic for treatment. This effort did address some of the enrollment problems but because we were dealing with a very ill population enrollment wasn't as high as we would have liked it to be. We did make efforts to reduce study burden by reducing questionnaire length and adding subject incentives, to reduce refusal rates. We estimate that preliminary data analysis will begin sometime in the following months (10/2007-12/2007). Thus, no analytical conclusions can be drawn at this time.

REFERENCES

None.

DOD Final Report
Leadership Core

Dr. Suzanne M. Miller, Ph.D.
Principal Investigator
Core Director

October, 2007

Psychosocial and Behavioral Medicine Program
Division of Population Science
Fox Chase Cancer Center

INTRODUCTION

Under the direction of the Leadership Core, the development of the Behavioral Center of Excellence in Breast Cancer (BCE) has been guided by a unifying cognitive-affective processing (CAP) approach to breast cancer prevention and control that has informed the specific hypotheses of each project and has dictated the relevant interventions and assessments, and that provides a multidisciplinary linkage across projects. The senior leadership and administrative support core component is designed to ensure scientific collaboration, guidance, and integration across the research projects and to promote the efficient administration of all the components of the BCE grant. Through collaboration between the principal staff on the main projects and other cores, the Leadership Core is able to broaden past and ongoing research by pursuing a closely coordinated research program to modify attitudes, behavior patterns, and lifestyles in ways that will ultimately reduce breast cancer incidence, morbidity and mortality effectively, thus directly addressing the mission for consequential behavioral research in breast cancer.

The specific aims of the Leadership Core are as follows:

Aim 1: To provide oversight, and management of, all aspects of the BCE to maximize the efficiency of its integrative, inter-coordinated organizational structure.

The Leadership Core for the BCE is intended to be a resource to the Center as a whole, as well as to function as the administrative resource for each of the individual projects.

Aim 2: To continue to develop, refine, and evaluate the overarching, unifying conceptual framework.

In order to continually refine the guiding theory of research within the BCE, the Leadership Core will integrate data across projects to more comprehensively address the dynamics of the interactions between construals and the other cognitions and affects that they prime and activate within the processing system, as the individual interprets, transforms, and acts on diverse types of cancer risk information (Miller & Diefenbach, 1998).

Aim 3: To oversee and enhance the centralized quality control mechanism for designing, refining, and evaluating the theoretically derived assessments and interventions.

The Leadership Core will function to ensure that the project investigators create and tailor the Cognitive-Affective Preparatory interventions to target the entire pattern of intervening cognitive and affective dynamics that underlie effective modulation of distress and long-term adherence to breast cancer prevention-control behaviors.

Aim 4: To develop actuarial predictive indices of cognitive-affective processing types.

With oversight from the Leadership Core, a goal of the BCE is to clarify and harness Person x Situation interactions emphasized by the C-SHIP model. This requires a shift from global to specific, contextualized analysis and assessments.

Aim 5: To oversee and guide the planning, development, and implementation of new BCE projects.

By building on the strong network of projects already proposed, the vision of the BCE is to develop further studies that are relevant to the CAP agenda and that interact synergistically with the ongoing work.

Aim 6: To administer the Training Program.

The Leadership Core will oversee the implementation of the pre- and post- doctoral training program through the identification of qualified candidates with ambitions to pursue careers in behavioral medicine and the development of communications to enhance cancer prevention and control.

BODY

According to our Statement of Work the plan during Years 2 through 3 was to accomplish the following tasks: 1) to convene Advisory Committee and scientific meetings; 2) to oversee implementation of core functions and to oversee initiation of projects and cores; 3) to implement the Training Program and, 4) implement meta-analysis and thematic integration of findings

Task 1. To convene the advisory committee and scientific meetings.

First, the External Advisory Committee, which was chosen to provide consultation for the BCE senior staff, held its first meeting in December 2002 at FCCC. Dr. Howard Leventhal, Board of Governors Professor of Health Psychology, and Director of the Institute of Health, Policy and Aging Research at Rutgers University, provided expert consultation in the theoretical application of cognitive-social principles to the assessment and development of the study interventions. Dr. Chanita Hughes, Assistant Professor in Psychology at the University of Pennsylvania provided expert consultation in cultural sensitivity with respect to intervention development and minority recruitment. In September 2007, Dr. Leventhal and Dr. Hayley Thompson provided expert consultation regarding issues related to aging and breast cancer survivors as well as recruitment strategies for hard to reach populations.

Second, Dr. Miller, Director of the BCE, continues to involve the Behavioral Center of Excellence in the organization of several national groups. This includes leading the Behavioral Oncology Interest Group at the American Society for Preventive Oncology. Dr. Miller, a Member of the Steering Committee, co-chaired the 2006 Annual Meeting of ASPO in Bethesda MD with a Pre-conference Day on Numeracy, entitled: “What Numbers Could Be: The Role of Numeracy in Understanding and Communicating Cancer Risk and Management Information”. This meeting consisted of talks followed by roundtable discussions facilitated by behavioral scientists to focus on advances at the intersection of behavioral science and oncology, and allowing interchange and discussion of behavioral science issues as they relate to cancer prevention. Dr. Miller was also a leading organizer of 2005 Society of Behavioral Medicine Cancer Special Interest Group (SIG) Pre-conference Day Roundtable Sessions on Decision

Making in Cancer (Annals of Behavioral Medicine, November 2006). The Annals of Behavioral Medicine is dedicating a special series to this Decision Making in the Cancer Context Pre-Conference Day with Dr. Miller as a guest editor. In 2006, Dr. Miller organized the 2006 Cancer SIG Pre-conference Day, *Health Disparities: Future Directions for Behavioral Medicine*. The results of this session are currently being prepared for publication. Dr. Miller is currently planning the 2007 Cancer SIG Pre-conference Day, *Cancer and Aging: Challenges and Opportunities Across the Cancer Control Continuum*. In 2007, Dr. Miller again led the organization of the 2007 Cancer SIG Pre-conference Day, *Cancer and Aging: Challenges and Opportunities Across the Cancer Control Continuum*. A special supplement in Cancer will include papers based on pre-conference day discussions. Dr. Miller is currently planning the 2008 Cancer SIG Pre-conference Day, entitled *Interpersonal Communication and Cancer Control: Emerging Themes*. As long-standing Co-Chair of the Cancer SIG, Dr. Miller has organized many Cancer SIG sponsored symposia, including this year's "The Great Debate: Positive psychology: How positive should we be?" and "Tobacco cessation in chronic disease: An urgent need and an under-recognized benefit."

Third, Dr. Suzanne Miller and other members of the BCE team presented a paper from the BCE projects, *Decision making among high risk women undergoing breast/ovarian genetic testing*, at the Annual Meeting of the Society of Behavioral Medicine, San Francisco, CA. March, 2006. A manuscript from this presentation is being submitted to the Annals of Behavioral Medicine. It represents an important addition to the literature by utilizing a mixed-method approach to assessing information processing through the use of an innovative talk-aloud assessment protocol.

Fourth, the Leadership Core has established the Behavioral Medicine Speakers Series at Fox Chase Cancer Center. The following speakers were invited to present their most current data to the Division of Population Sciences:

- Dr. Karen Hurley, Memorial Sloan-Kettering Cancer Center, spoke on, "Person-centered theories: New directions in behavioral oncology research" on December 6, 2005.
- Dr. Karen Sepucha, Massachusetts General Hospital/Harvard Medical School Health Decision Research Unit, spoke on, "Understanding and Improving the Quality of Breast Cancer Treatment Decisions" on January 17, 2006.
- Dr. Catharine Wang, Fox Chase Cancer Center, spoke on, "Public Health Efforts in Familial Risk Assessment" on February 14, 2006.
- Dr. Carolyn Fang, Fox Chase Cancer Center, spoke on, "Mindfulness-Based Interventions to Enhance Health" on April 4, 2006.
- Dr. Paul Han of National Institutes for Health spoke on, "Predictors of Decisions Between Risk Reducing Salpingo-Oophorectomy and Ovarian Cancer Screening in Women at Increased Risk of Ovarian Cancer" on September 12, 2006.
- Ms. Linda Fleisher, Fox Chase Cancer Center, spoke on "Translating Science & Evidence into Cancer Control Practice" on May 29, 2007
- Dr. Melissa Napolitano, Temple University, spoke on "Exercise and Cancer Survivorship" on May 31, 2007.

Dr. Miller and Dr. Buzaglo continue to work with the FCCC Community Clinical Oncology Program (CCOP) Research Base to expand hospital-based research into the community.

Through the stimulation of research efforts into the community, the FCCC CCOP Research Base will provide cancer patients, their families, and high-risk individuals access to new prevention and control studies closer to home. CCOP investigators are currently conducting an intervention for breast cancer survivors using the NCI publication, Facing Forward, “Efficacy and Feasibility of a Psychosocial Intervention within the CCOP Context: Evaluation of the Facing Forward Guide to Facilitate Life after Active Cancer Treatment”. Recruitment to this trial began in September of 2006. We have recruited 69 participants with an overall target of 300 evaluable participants over the next year from the 7 CCOP sites in the community. Dr. Buzaglo has presented at bi-annual CCOP conferences and is actively involved in the CCOP Steering Committee which meets on a monthly basis.

Dr. Miller continues to serve as a member of the Board of Directors of the New Jersey Health Care Quality Institute and as a member of the National Quality Forum’s *Quality of Cancer Care Measures* project where she serves on the Symptom Management/End of Life Care Technical Panel. In addition to symptom management and end-of-life care, this project focuses on colorectal and breast cancer diagnosis and treatment. The Technical Panel is charged with conducting an initial assessment to evaluate candidate performance measures for their validity, which must occur before the Project’s Steering Committee will consider recommending the measure to the National Quality Forum for endorsement.

Task 2. To oversee implementation of core functions and to oversee initiation of projects and cores.

The Leadership Core held monthly BCE meetings. Principal Investigators, Co-Investigators, Project Managers of the various BCE projects and Core staff attended these meetings to provide an opportunity for investigators to exchange ideas and provide input across studies. Agenda items included: 1) Updates from each project and core; 2) Training Program status; 3) DOD reporting requirements and IRB documentation; 4) Standardization of assessment tools across studies to maximize opportunities for meta-analysis; and 5) Cooperative strategies to enhance recruitment across studies. Meetings minutes were kept to record the current status of each study. Specifically:

- **Recruitment for Phase 2 of project 1:** Two hundred twenty one calls were received, but only 85 callers met the eligibility criteria, and out of these 50 consented to participate in the study. Thirty-five have completed baseline surveys and 23 have completed 6-month follow-up surveys. Amendments were submitted and approved by the FCCC and DOD IRBs to exclude the criteria pertaining to income and broaden the eligibility criteria to include second degree relatives. Radio and newspaper advertisements were no longer utilized. Four sites allowed us to recruit through their organizations using flyers. These sites include community and religious organizations, a health seminar, and a breast cancer survivor’s mentorship program. An additional amendment was submitted to the FCCC IRB in September 2006, and was subsequently approved. Upon FCCC and DOD IRB approval, flyers were distributed to the four sites inviting potential participants to call the toll free telephone number. This new recruitment strategy yielded 11 additional participants, all of whom completed baseline assessments. Their follow-up assessments are pending and due to be completed in November and December of 2007. A total of 58 women consented to participate in Project 1, Phase 2.

Of those 58 women, 46 completed baseline assessments, and 23 completed 6-month follow-up assessments. A total of 11 women have outstanding 6-month follow-up assessments.

- Recruitment for Project 2 is still in progress. A total of 520 potential participants have been contacted and of these, we have accrued and randomized 157 participants (83 tailored intervention group, 74 control group). Of these participants, 132 have completed the 12-month follow up.
- Recruitment for Project 3 is still in progress. Including the pilot study, 826 patients were evaluated for eligibility and 163 eligible participants were approached. 76 participants gave verbal consent, 60 provided written consent, 50 completed the baseline survey, 44 completed the intervention, 39 completed the 2 week booster session, 33 completed the one month follow-up, 19 completed the 6 month follow-up, and 14 completed the 12 month follow-up.
- Despite efforts to increase enrollment by approaching patients in-person and increasing awareness of our project among the oncologists treating patients at Fox Chase Cancer Center, the recruitment figures for project 4 were lower than originally anticipated. Low recruitment figures continue to stem from two primary causes; 1) we have identified fewer eligible individuals than previously estimated, and 2) we have experienced a higher refusal rate than anticipated. Our sample size at this point is 53. 29 women were assigned to the Communication and Support skills condition and 24 women were assigned to the supportive condition. Of the 29 women assigned to the Communication and Support skills condition, twenty have completed all six sessions and nine have dropped out of the study. Of the 24 assigned to the Supportive counseling condition, seventeen women have completed all 6 sessions and seven have dropped out. Thirty-five of our 53 participants have completed the first follow-up and twenty-eight have completed the second follow-up survey.

Task 3. To implement the Training Program.

The following has been implemented to support the BCE Training Program:

The Leadership Core holds the responsibility of disseminating an announcement about pre- and post-doctoral fellowship opportunities, developing an evaluation procedure, arranging for candidate interviews, selecting candidates, and training the post-doctoral fellows. The following review criteria are used to evaluate potential candidates: Ability in Written Communication, Familiarity with Behavioral Oncology in General, Familiarity with Breast Cancer in Particular (Behavioral and Medical issues), General Research Experience, Apparent General Research Proficiency, Commitment to Research Career in Behavioral Oncology/Cancer Prevention and Control, Quality and Relevance of Academic Training, Enthusiasm for Fellowship, Convergence Between BCE Projects and Applicant's Experience, Convergence Between BCE Projects and the Applicant's Career Goals.

Pagona Roussi, Ph.D., returned to the Psychosocial and Behavioral Medicine Program in September/October 2004, September 2005, September/October 2006 and September/October 2007. Dr. Roussi has been serving as a trainee with Dr. Miller and members of the research team on several ongoing grants. Dr. Roussi comes from Aristotle University of Thessaloniki, Thessaloniki, Greece offering expertise in stress and coping with major life events, with a special interest in serious illnesses. Dr. Roussi has a Ph.D. in Chemistry earned at Imperial College,

London University, London, England in 1977. Since earning her Ph.D. in Clinical Psychology at Temple University, Philadelphia, Pennsylvania in 1995 Dr. Roussi has taught in the Department of Philosophy and Social Studies at the University of Crete, Crete, Greece as a Visiting Assistant Professor as well as in the Department of Psychology at Aristotle University of Thessaloniki, Thessaloniki, Greece. She has several publications, both independently and in collaboration with Dr. Miller and other Investigators. Her responsibilities at FCCC include analyzing data, writing manuscripts, and providing consultation and assistance with the designing of new interventions. Specifically, she has been involved in the development of the intervention protocol for Project 3 and for data-analytic plans.

Mary Ropka, Ph.D., R.N., F.A.A.N., joined the faculty at Fox Chase in May 2004 as an Associate Member in the Division of Population Science and has been involved in BCE as a mentee. She also holds adjunct appointments as Associate Professor in the Department of Public Health Sciences at the University of Virginia School of Medicine and in the School of Nursing. Dr. Ropka is a clinical epidemiologist and oncology nurse who has a long-standing track record of interdisciplinary work and building new research programs and teams. She has experience with diverse study approaches, including multi-site clinical trials, survey research, observational designs, focus group studies and other qualitative approaches, and systematic reviews. Dr. Ropka recently completed a 5-year K07 Cancer Prevention (2001 – 2006), Control, and Population Sciences Career Development Award from NCI. The K07 was focused on decision support, behavioral cancer genetics, and cancer prevention and control in order to develop and test patient decision support interventions related to hereditary cancer risk. Dr. Miller was Co-Sponsor for her K07. In addition, Dr. Ropka is assisting Dr. Miller on the following: (1) the Behavioral Research Core Facility, of which Dr. Miller is the Director; (2) Dr. Ropka's K07 study, "Decision Making Needs and Family Communication When Dealing With Hereditary Cancer Risk Decisions – A Qualitative Pilot Study", for which Dr. Miller is a co-investigator and data are currently being analyzed; (3) Dr. Ropka's March 2007 R21 revised application, "Facilitating Web-based Decision Support For Hereditary Cancer Risk", which was recently approved for funding by NINR; (4) the CISRC P01 grant funded by NCI, of which Dr. Miller is PI of the Intervention Development and Measurement Core; (5) submitting Dr. Ropka's revised R21 grant application in July 2007 for which Dr. Miller is a co-investigator, "Benign Breast Disease: Cognitive-Affective Responses and Risk Reduction Behaviors" in response to Program Announcement PA-06-351, "Exploratory Grants for Behavioral Research In Cancer Control (R21)".

Catharine Wang, Ph.D. joined the Psychosocial and Behavioral Medicine Program in August 2005 as an Assistant Member in the Division of Population Science at FCCC and is involved as a mentee in the BCE. She has an extensive background in developing and evaluating tailored interactive multimedia and behavioral interventions. Prior to her appointment at FCCC, Dr. Wang was involved in several projects in collaboration with the Health Media Research Lab (now the Michigan Center for Health Communication Research) at the University of Michigan, led by Dr. Strecher. These projects included the development of an interactive CD-ROM program for BRCA1/2 education and counseling, and tailored health communication interventions to address multiple behavioral risk factors such as smoking cessation, physical activity and diet. In addition, Dr. Wang has a background in the area of decision research. She has collaborated with researchers at the University of Michigan to examine how various

communication aids, such as graphic images or pictographs, may be used to improve the comprehension of risk communication and modify the influence of patient testimonials in treatment decision making. Dr. Miller is currently mentoring Dr. Wang in the application of theory to behavioral interventions and evaluation of public health programs related to breast cancer risk and survivorship. Currently, Dr. Wang is Principal Investigator on two grants to 1) examine the impact of causal attributions for breast cancer and 2) overcome genetic literacy barriers among underserved minority populations. In addition, she is a Co-Investigator on a grant to develop and test a web-based decision support intervention system for individuals concerned about hereditary breast cancer risk.

Amy Lazev, PhD., joined the Psychosocial and Behavioral Medicine Program in July 2003 as an Assistant Member in the Division of Population Science at FCCC. She currently holds a Cancer Prevention Research Fellowship from the American Society of Preventive Oncology/Cancer Research & Prevention Foundation to study college smoking behavior. She is a clinical psychologist with over 10 years of experience developing and conducting treatment outcome studies in smoking cessation. Her research has focused on special populations including pregnant and postpartum women, low-income and minority populations, college students, persons living with HIV/AIDS and cancer patients. She has been funded with an R25 NCI training grant mentored by Dr. Suzanne Miller. She has also been the Principal Investigator on an American Lung Association grant examining social support and depression among pregnant and postpartum women who smoke and on an American Cancer Society grant examining smoking behavior in the college-age population. She is currently collaborating with Dr. Miller and the Maternity Care Coalition, a community-based service and research organization, on a grant submission for a smoking cessation intervention for underserved pregnant and postpartum women.

Pamela J. Shapiro, Ph.D., joined the Psychosocial and Behavioral Medicine Program in May 2006 as an Assistant Member in the Division of Population Science at FCCC. She previously held a Postdoctoral Fellowship in the Department of Psychiatry and the Abramson Cancer Center of the University of Pennsylvania. Dr. Shapiro is a cognitive psychologist whose research interests include the neurocognitive sequelae of cancer diagnosis and treatment, health-related quality of life, survivorship, and issues of concern to women at risk for hereditary breast and ovarian cancers (HBOC). She is currently conducting an NCI funded study (1 R03 CA128397-01), *Psychosocial Predictors of Cancer-Related Cognitive Change*, to examine the real-life cognitive difficulties women with breast cancer experience across the cancer trajectory. She is collaborating with Drs. Miller and Barsevick to develop projects examining cognitive outcomes among patients receiving platinum based chemotherapy and to implement cognitive assessments among older patients receiving care at FCCC. Dr. Shapiro recently submitted an application for an NCI K07 Career Development Award to examine a biopsychosocial model of cancer-related cognitive change and explore the utility of a serum biomarker of cognitive decline among breast cancer patients.

Douglas Hill, PhD., joined the Psychosocial and Behavioral Medicine Program as a Senior Project Manager in February 2006. Dr. Hill has a doctorate degree in Social Psychology and a research background on health beliefs, changing health behaviors, and public health policy. He was mentored by Dr. Suzanne Miller and Dr. Joanne Buzaglo within the BCE in research

methodology and design, and behavioral oncology. He currently has accepted a position at the Children's Hospital of Philadelphia.

Etyia Faison, M. Ed., joined the Psychosocial and Behavioral Medicine Program as a Project Manager in June 2006. She has a counseling background in individual, group, and family therapy and a research background in nutritional and epidemiological research. She is being mentored by Dr. Suzanne Miller and Dr. Joanne Buzaglo within the BCE in research methodology and design, and behavioral oncology with an emphasis on healthcare disparities among racial/ethnic underserved minorities.

Jaime Marks, MS, joined the Psychosocial and Behavioral Medicine Program as a Health Educator in July 2006 after completion of her Masters in Human Development and Family Studies at Pennsylvania State University. She was mentored by Dr. Suzanne Miller and Dr. Joanne Buzaglo within in the BCE in breast cancer research with an emphasis on survivorship and psychosocial correlates of cancer screening and prevention behavior among underserved populations.

Elizabeth Bernabeo, MPH, joined the Psychosocial and Behavioral Medicine Program in January 2004, and is involved as a mentee in the BCE. She currently holds a Master Degree in Public Health from Temple University and she is completing her Ph.D. in Social Welfare at School of Social Work and Social Research, Bryn Mawr College. Elizabeth Bernabeo is being mentored by Dr. Suzanne Miller and Dr. Joanne Buzaglo in decision-making process in cancer context, and psychosocial aspects of decision-making in the context of genetic testing. She is conducting her dissertation project: "Decision Making among High-Risk Women Undergoing Breast/Ovarian Genetic Testing" under the supervision and mentorship of Dr. Miller and Dr. Buzaglo.

Elizabetta Razzaboni, Ph.D., joined the Psychosocial and Behavioral Medicine Program in August 2004 and worked with the research team for eight weeks. She came to FCCC from the Department of Psychology at the University of Bologna, Bologna, Italy. She was actively involved in reviewing BCE focus group transcripts with a special focus on qualitative analysis. Drs. Miller and Buzaglo mentored her with respect to the application of cognitive-social theory to the development of assessment and behavioral intervention protocols for women at high risk for breast and ovarian cancer. Dr. Razzaboni is a member of an interdisciplinary oncology team in Bologna established to create a program for state-of-the-art care for women at familial risk for breast and ovarian cancer and is continuing to work collaboratively with BCE.

Catia Ghinelli, Ph.D., returned to the Psychosocial and Behavioral Medicine Program in August-September 2005 as a mentee in the BCE. She originally came to FCCC from the Department of Psychology at the University of Bologna, Bologna, Italy in the summer of 2003 at which time she translated study protocols related to breast cancer survivorship and lymphedema. She continues to collect data on women diagnosed with early stage breast cancer and is actively involved in comparing cross-cultural datasets relevant to the BCE. Drs. Miller and Buzaglo provide ongoing guidance in the data collection and analysis.

Chana Gorodischer, CSW, Coordinator of the Eshkol Breast Health Center, Soroka University Medical Center, Ben Gurion University of the Negev, Israel. Ms. Gorodischer spent a two-week

internship in August 2005 to study the cognitive-social model utilized to develop and assess the BCE behavioral protocols with a special focus on BCE 3, *Facilitating Re-entry Following Adjuvant Treatment for Primary Breast Cancer* as well as a related study entitled *Efficacy and Feasibility of a Psychosocial Intervention within the CCOP Context: Evaluation of the Facing Forward Guide to Facilitate Life after Active Cancer Treatment* (P.I. Dr. Suzanne M. Miller). Both of these ongoing funded projects will provide the foundation on which to build a research program that assesses the psychosocial needs of women who have undergone treatment for breast cancer as well as the development of innovative health communications and evaluation of the comprehensive psychosocial programs already in place at the Soroka Breast Health Center in Beer Sheva, Israel.

Shawna V. Hudson, Ph.D., joined the FCCC Division of Population Science in March 2007 as an Adjunct Associate Member. She is the Director of Community Research for The Cancer Institute of New Jersey (CINJ), the only NCI designated comprehensive cancer center in New Jersey. She is also an Assistant Professor of Family Medicine at the UMDNJ-Robert Wood Johnson Medical School. Dr. Hudson is a medical sociologist and her research spans the cancer prevention/control continuum from preventive cancer screening in primary care practices to cancer clinical trial participation during treatment to follow-up screening and surveillance for cancer survivor care. Her studies have been focused in three main areas: (1) exploring cancer disparities in treatment and screening settings; (2) examining determinants of preventive cancer screening in primary care settings; and (3) examining organizational cultural factors in primary care practices that facilitate participation in practice based research and increased use of evidence based guidelines. She recently submitted with Dr. Miller as her mentor an NCI K01 proposal, "Life After Cancer: Examining Survivor Transitions from Specialist to Primary Care" to examine early stage breast and prostate cancer survivors' use of oncologists and primary care providers in their follow-up cancer care. She is also an evaluator for two Susan G. Komen Breast Cancer Foundation of North Jersey Affiliate clinical trial projects that examine whether the use of ethnically-matched patient navigators increases minority patient recruitment to breast cancer clinical trials.

The Summer Internship program was established in 2002 to provide training opportunities to students at the high school, undergraduate and graduate levels in the area of behavioral research within the context of breast cancer prevention and control to encourage future leaders in the field and to provide a source of candidates for the Training Program. Three interns joined us in the summer of 2006. James Wise, a senior at Pennsylvania State University, joined FCCC in June 2006 as a research intern. He worked on integrity checks and data entry for project 3. Yana Anokhnia, a senior attending Bensalem High School in Bensalem, PA, joined FCCC in July 2006 and helped with screening participants for eligibility and with recruitment calls for project 3. Bridget Brady, a senior at Millersville University, joined FCCC in July 2006. She helped with screening participants for eligibility and recruitment calls for project 3, and with contacting organizations for project 1. In 2006 Stacey Abraham and Marina Mathew, both high school students at Central High School in Philadelphia joined us. During their time with FCCC, they assisted with screening participants for eligibility and recruitment calls for project 3. Komaira Ferdous, a senior attending Temple University's Public Health program joined FCCC in September of 2006. She contributed to our Tailored Communication for Cervical Cancer Risk project by making follow-up calls, conducting assessments, performing telephone interventions,

conducting literature searches, and lending extensive support to a sub-study which collected data on women's thoughts and feelings about the new HPV vaccine. Jamilia Sherls, a freshman attending Drexel University's School of Public Health joined FCCC in September of 2006. The primary focus of Jamilia's internship was assisting with the patient Navigator project. In 2007 4 new interns joined the Psychosocial and Behavioral Medicine department and contributed in various ways to our numerous ongoing projects. In Feb 2007 Michael Bender, a Post Baccalaureate Pre-Medical Program student attending Bryn Mawr College, and Avash Kalra, a post-baccalaureate Pre-Medical Student attending the University of Pennsylvania both joined FCCC. Michael assisted with recruitment for, and dissemination of information about the Prostate Risk Assessment Program. Michael and Avash both worked on the American Cancer Society Pregnant and Smoking Study performing data entry. In May 2007, Helen Schmidheiser, a senior attending Penn State University Abington joined FCCC. Helen worked on Project 3 making recruitment calls, mailing printed materials to patients, and conducting telephone interventions. Imana Melton, a student pursuing graduate level study in Forensic Science Philadelphia College of Osteopathic Medicine joined FCCC in August of 2007, and continues to assist with recruitment on the Psychosocial Predictors of Cancer related Cognitive Change project.

Task 4. To implement meta-analysis and thematic integration of findings.

An extensive meta-analysis will be conducted, as planned in Task 4, upon the completion of data collection for the studies within the BCE.

The Leadership Core has contributed an extensive list of articles based on its literature search on breast cancer risk to the library of the Behavioral Research Core Facility (BRCF) at Fox Chase Cancer Center under the direction of Dr. Suzanne Miller. The BRCF provides the necessary infrastructure and resources to integrate basic and applied bio-behavioral and psychosocial research across the spectrum of cancer prevention and control research. Its mission and function are synergistic with that of the BCE. The BRCF library serves as an NCI-funded resource to investigators throughout the institution.

KEY RESEARCH ACCOMPLISHMENTS

- The continuation of monthly BCE meetings.
- The following steps have been implemented to support the BCE training program:
 - The continuing support of the BCE Training Program Committee that oversees the development and implementation of promotional strategies to enhance recruitment of qualified candidates for the pre- and post-doctoral fellowships.
 - Pagona Roussi, Ph.D., returned to the Behavioral Medicine Program as a consultant on the various projects within the BCE.

- Catia Ghinelli, Ph.D., joined the Behavioral Medicine Program in August 2005 as a visiting researcher providing consultation in cross-cultural data collection and quantitative data analysis for the projects within the BCE.
- Pamela J. Shapiro, Ph.D., was hired to fill the remaining post-doctoral position within the Training Program. She previously held a Postdoctoral Fellowship in the Department of Psychiatry and the Abramson Cancer Center of the University of Pennsylvania . Her research interests include health-related quality of life, the cognitive sequelae of cancer diagnosis and treatment, and issues of concern to women at risk for hereditary breast and ovarian cancers (HBOC).
- The establishment of a collaboration with the Eshkol Breast Health Center, Soroka University Medical Center, Ben Gurion University of the Negev, Israel to translate BCE protocols and develop innovative health communications and evaluation of the comprehensive psychosocial programs already in place at the Soroka Breast Health Center in Beer Sheva, Israel. Dr. Buzaglo visited the Eshkol Breast Health Center in Ben Gurion University of the Negev in August 2007 and met with collaborators Dr. Michael Koretz, Chair of Surgery, and Ms. Gorodischer to facilitate implementation of study protocols.
- The Summer Internship Program and the Yearly Internship Program continued successfully for its fifth year in providing training opportunities to students at the high school, undergraduate and graduate level in the area of behavioral research within the context of breast cancer prevention and control to encourage future leaders in the field.
- The continuation of the Behavioral Oncology Interest Group at the American Society for Preventive Oncology (ASPO).
- Continued leadership of the Cancer Special Interest Group of the Society of Behavioral Medicine (SBM).
- Preparation and publication in 2006 of two volumes that will extend the theoretical model across the cancer continuum, including genetic risk, and provide an integrative synthesis of the behavioral medicine field. The titles of these volumes are: “Individuals, families and the new era of genetics: Biopsychosocial perspectives” and “Handbook of Cancer Control and Behavioral Science: A Resource for Researchers, Practitioners, and Policy Makers”
- Collaboration with Al Marcus, Ph.D., of the AMC Cancer Research Center, on a research consortium using the Cancer Information Service, recently funded by the National Cancer Institute.
- The Leadership Core applied for and received DOD approval for a no-cost one-year extension.

REPORTABLE OUTCOMES AND BIBLIOGRAPHY OF PUBLICATIONS

At this time, the Leadership Core provided integrative oversight and management of all aspects of the BCE to maximize the efficiency of its inter-coordinated organizational structure. The Core developed, refined, and evaluated the overarching, unifying conceptual framework in its efforts to oversee and enhance the centralized quality control mechanism for designing, refining, and evaluating the theoretically-derived assessments and interventions. The Core remained active in the ongoing maintenance of the Training Program.

- **Presentations:**

Miller, S.M., Buzaglo, J.S., Bernabeo, E., Roussi, P., Daly, M.B., Pope-Mabe, M. Annual Meeting of the American Society of Preventive Oncology. Poster on: Decision making among high risk women undergoing breast/ovarian genetic testing. Bethesda, MD, February, 2006.

Miller, S.M. Invited Speaker on Cognitive and emotional aspects of the response to cancer risk. Stress and Anxiety Research Society (STAR), University of Crete, Rethymnon, Crete, Greece. July, 2006.

Miller, S.M. Invited Speaker on New Research Directions in Aging and Disparities: Cancer control in action. Sponsored by Case Western Comprehensive Cancer Center, Case Western Reserve University, Cleveland, OH September, 2006.

Miller, S.M. Invited Presenter, Psychosocial effects in chronic disease, as part of an International Conference on Human Sexualities, Hyderabad, India , February, 2007.

Miller, S.M. Invited Co-Chair and Moderator, Symposium on the American Cancer Society and the National Cancer Institute: Ongoing Scientific Initiatives and Extramural Opportunities. Annual Meeting of the Society of Behavioral Medicine, Washington, DC, March, 2007.

Miller, S.M. Invited Co-Chair, Symposium on Assessment in Older Persons with Cancer. Annual Meeting of the Society of Behavioral Medicine, Washington, DC, March, 2007.

Miller, S.M. Invited Co Chair, Symposium on Applying Biomedical Informatics to Cancer Screening: The Future is Now. Annual Meeting of the Society of Behavioral Medicine, Washington, DC, March, 2007.

Miller, S.M. Invited Discussant, Pseudoscience, Science and Scientism in Cancer and Cardiovascular Health: Establishing Pathways to Evidence-Based Practice. Annual Meeting of the Society of Behavioral Medicine, Washington, DC., March, 2007.

Miller, S.M. Invited Chair, Session on Survivorship: From Molecular Epidemiology to Symptom Management. Annual Meeting of the Society of Preventive Oncology, Houston, TX, March, 2007.

Miller, S.M. Invited Co-Chair, Annual Meeting & Scientific Session, Society of Behavioral Medicine, Cancer SIG Pre-Conference Day: Cancer and Aging: Challenges and Opportunities Across the Cancer Control Continuum. Annual Meeting of the Society of Behavioral Medicine, Washington, DC, March, 2007.

Miller, S.M. Invited Chair, Session on Survivorship: From Molecular Epidemiology to Symptom Management. Annual Meeting of the Society of Preventive Oncology, Houston, TX, March, 2007.

Miller, S.M. Invited Presenter, Cancer Risk Prevention Educational Workshop. American Society of Preventive Oncology, Houston, TX, March 2007

Miller, S.M. Invited Chair, Session on Translating Genetics into Chronic Disease Prevention: Implications for Practice and Research. Annual Meeting of the Society of Preventive Oncology, Houston, TX, March, 2007.

Miller, S.M. Invited Presenter. PAC3 Third Annual Summit, State College, PA, March 2007.

Miller, S.M. Invited Speaker, Grand Rounds, Behavioral Approaches to Cancer Risk and Disease. University of Texas, M.D. Anderson Cancer Center, Houston, TX. June, 2007.

Miller, S.M., Invited Plenary Speaker, 10th Anniversary, Cancer and Aging, New Jersey Health Care Quality Institute Princeton, NJ, June 2007.

Miller, S.M., Invited Presenter, Cancer Research and Prevention Foundation, Patient Responsibility/Decision Making, Dialogue for Action, Trenton, NJ June 2007.

Miller, S.M. Invited Speaker, Grand Rounds, Psychosocial Factors in Cancer Screening, Diagnosis and Survivorship, Memorial Sloane Kettering Cancer Center, New York, NY, September, 2007.

Miller, S.M., Co-chair Patient Navigation Workshop Conference, Philadelphia, PA, October 2007.

Miller, S.M. Invited Presenter, Center for Information Therapy Conference, Park City, UT, October 2007.

- **Publications:**

Miller, S.M., Fleisher, L., Roussi, P., Buzaglo, J.S., Schnoll, R.A., Slater, E., et al. (2005). Facilitating informed decision making about breast cancer risk and genetic counseling among women calling the NCI's Cancer Information Service. *Journal of Health Communication, Special Issue on The National Cancer Institute's Cancer*

Information Service: A New Generation of Service and Research to the Nation, 10, 119-136.

Hurley, K., Miller, S.M., & Rubin, L.R. (2006). The individual facing genetic issues: Information processing, decision making, perception, and health-protective behaviors. In S.M. Miller, S. McDaniel, J. Rolland, & S. Feetham. (Eds.), *Individuals, families and the new era of genetics: Biopsychosocial perspectives*. (pp. 274-319) New York: Norton Publications.

Miller, S.M., Daly, M.B., Sherman, K., Fleisher, L., Buzaglo, J.S., Godwin, A., & Scarpato, J. (2006). Psychosocial Processes in Genetic Risk Assessment for Breast Cancer. In S.M. Miller, S. McDaniel, J. Rolland, & S. Feetham (Eds.), *Individuals, families and the new era of genetics: Biopsychosocial perspectives*. New York: Norton Publications.

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Miller, S.M., Bowen, D., Clark, M., Emmons, K., Lyle, J.L., Gritz, E., Marlee, L., et al. (in press). Primary Prevention, Aging, and Cancer: Overview and Future Perspectives. *Cancer*.

Buzaglo, J.S., Millard, J.L., Ridgway, C.G., Ross, E.A., Antaramian, S.P., Miller, S.M., et al. (in press). An Internet Method to Assess Cancer Patient Information Needs and Enhance Doctor-Patient Communication: A Pilot Study. *Journal of Cancer Education*.

Meropol, N., Buzaglo J.S., Millard, J., Damjanov, N., Miller, S.M., Ridgway, C., et al. (in press). Barriers to clinical trial participation as perceived by oncologists and patients. *JNCCN - Journal of the National Comprehensive Cancer Network*.

Patenaude, A.F., Peterson, S.K., Geller, G., Gritz, E.R., Hadley, D.W., Halbert, C.H., Miller, S.M., Sankar, P., Schwartz, M., Tercyak, K.P., Vernon, S.W., & Press, N. (in press). Adoption of risk management recommendations by individuals with inherited predisposition to breast/ovarian and colorectal (HNPCC/Lynch Syndrome) cancer: Psychological and behavioral predictors and outcomes. *Journal of Clinical Oncology*.

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Diefenbach, M.A., Miller, S.M., Porter, M., Peters, E., Stefanek, M., & Leventhal, H. (in press) Emotions and health behavior: A self-regulation perspective. In M. Lewis, J.M. Haviland-Jones, & L.F. Barrett (Eds.), *Handbook of Emotions*, 3rd edition. New York: Guilford Publishing.

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CONCLUSION

Members of the BCE successfully assisted all research teams accomplish their tasks throughout the period of funding. Our efforts focused on the development of the necessary infrastructure between project staff and the other core facilities in order to facilitate synergistic research efforts and integrative findings across the multiple projects.

REFERENCES

None

DOD Final Report
Communications Core

Suzanne M. Miller, Ph.D., Principal Investigator
Linda Fleisher, MPH, Core Director

October, 2007

Psychosocial and Behavioral Medicine Program
Division of Population Science
Fox Chase Cancer Center

INTRODUCTION

The Communications Core has provided critical support and services for the research projects in the Behavioral Center of Excellence in Breast Cancer (BCE). The Communications Core builds on and extends the infrastructure, resources and expertise of the FCCC Behavioral Core to include state-of-the art communications theory and applications.

The Communications Core has two primary functions. The first, descriptive function consists of assessing information needs and culturally specific beliefs of populations targeted by the different Center projects. The second primary function of the Communications Core is to successfully translate this information into effective communication messages and strategies that meet the needs of the target population. To this end, the Communications Core conducts in-depth needs assessments of the target populations through focus groups for each individual research project; analyzes the information obtained; and assists in developing appropriate patient-tailored health communications.

Specifically, the aims of the Communications Core are:

Aim 1: To provide linkages to the FCCC Behavioral Core for assistance in evidence-based behavioral approaches and measures.

Aim 2: To expand the Behavioral Core resources to include communication theory and applications.

Aim 3: To facilitate the assessment of information needs of the target populations through focus groups.

Aim 4: To provide consultation in the development of interventions using behavioral, health education and communication principles and theories.

Aim 5: To provide formative evaluation services (e.g. implementation and analysis) to inform the development and pilot testing of interventions for specific populations.

By utilizing the Communications Core for all research projects an economy of scale is created with a synergistic impact that benefits and informs each of the projects as well as the entire Behavioral Center of Excellence.

These goals are achieved through a structured consultation and implementation process that includes an initial contact and needs assessment phase, a planning phase, and an implementation and follow-up phase. Throughout these phases, members of the Communications Core and members of the individual research projects have been in frequent contact to ensure that the objectives of the individual research projects are achieved.

BODY

The Communications Core over the course of the Center has worked closely with Investigators to develop assessment approaches (e.g. focus groups) to gather critical information to address specific needs of the target audiences, integrate communication theory into the interventions and provide consultation for all projects. The Communications Core has also developed a Resource Repository of literature and resources on communications, tailoring, cultural implications and literacy.

In the past year, the Core has focused on the final phases of intervention implementation, manuscript preparation and development and strengthening linkages to the FCCC Behavioral Research Core. The Communications Core has been successful in supporting each research project as specified in the Statement of Work. Over this past year, we have continued to expand the resource library, identify potential publications regarding the development of the interventions, assist in the development and refinement of project recruitment strategies. Underlying each of these accomplishments has been the Core's effort to integrate the Communications Core with the FCCC Behavioral Research Core Facility.

KEY RESEARCH ACCOMPLISHMENTS

- Attend and participate in monthly Center meetings.
- Members of the Communications Core have continued to augment the library of the Behavioral Research Facility with articles from the communications literature. Additional resources on cultural issues have been added. This resource is made available to all members of the BCE, as well as the wider community of researchers at FCCC.
- The synergistic relationship between the Core and the FCCC Behavioral Research Core has resulted in expanded resources to support recruitment approaches and strategies for researchers interested in expanding participation among minorities and community organizations.

Further, project-specific accomplishments follow:

- **Project I.** In collaboration with project staff the Communications Core has been integrally involved in manuscript development on focus group results. The Core also has contributed to the refinement and improvement of the project's recruitment strategies. The Core helped to identify four recruitment sites within the community and form partnerships with these organizations and individuals. Moreover, the Communications Core utilized the FCCC Behavioral Research Core as a resource for evaluating and improving recruitment communication tools to be used in the refine recruitment efforts (e.g., reviewed recruitment flyers).
- **Project II.** All interventions have been reviewed and implemented. Discussions regarding manuscripts have been initiated.

- **Project III.** Members of the Communications Core are integrally involved in the development of a manuscript that summarizes findings from the focus group data around patient barriers to adaptive transition from breast cancer treatment to survivorship.
- **Project IV.** The research team and members of the Communications Core have consulted and identified additional opportunities for recruitment.

REPORTABLE OUTCOMES AND BIBLIOGRAPHY OF PUBLICATIONS

Other than the key research accomplishments detailed above there are no reportable outcomes.

CONCLUSION

Members of the Communications Core have successfully assisted all research teams accomplish their tasks during their fifth year. Our efforts have focused on finalizing assessment and materials and analysis of focus group data to inform study procedures, protocols and materials. The Core has provided ongoing feedback at the monthly meetings and provided strategies for recruitment. We have also continued to add to the BRCF library by identifying and including key health communication research articles.

REFERENCES

None

DOD Final Report
Informatics Core

Suzanne M. Miller, Ph.D., Principal Investigator
Eric Ross, Ph.D., Core Director

October, 2007

Psychosocial and Behavioral Medicine Program
Division of Population Science
Fox Chase Cancer Center

INTRODUCTION

The varied populations studied in this Behavioral Center of Excellence in Breast Cancer (BCE) and the complexity of the designs required the development of study-specific computer based tools to provide project management and coordination; and for the collection, validation, storage, retrieval and analysis of data. The projects contained in this BCE include: Understanding Breast Cancer Risk Assessment and Screening Behavior Among the Underserved, Cancer-A Teachable Moment Within the Family: From Concept to Community, Facilitating Re-entry Following Treatment for Primary Breast Cancer, and Impact of a Communication Skills versus a Supportive Therapy Intervention for Women with Metastatic Breast Cancer. The objective of the Informatics Core (IC) was to facilitate BCE research by providing (1) a central repository for all of the data included in the research, (2) data entry and validation services and (3) report generation and standard statistical programming services. Included in this core data repository are: a) socio-demographic data on study populations, b) clinical information, c) family history, d) psycho-social data, e) health history data, f) quality of life data, g) cancer screening data, and h) diet data.

The specific aims of the core were:

Aim 1: To provide computer-based tools that facilitate the entry, storage, manipulation and retrieval of the large quantities of data generated in the proposed research.

Aim 2: To ensure the accuracy of the data maintained in the database by developing human and software based data consistency and quality control systems.

Aim 3: To provide high-quality data entry services.

Aim 4: To organize and maintain the database to maximize accessibility, while maintaining strict confidentiality.

Aim 5: To provide statistical computing support.

BODY

All core activities involved an ongoing collaborative effort between IC personnel and project research teams. For example, the design of studies and data collection instruments was the responsibility of the study investigators. However, after examination of the surveys and study design, IC personnel often made suggestions on how to modify specific aspects of the study execution plan to make them more amenable to implementation using computer based techniques. During the software development phase, facility staff and investigator interacted frequently to ensure that the resulting information system met the needs of the projects. The interaction between the development staff, investigators and research teams continued throughout the life of the projects.

The next few sections provide a more detailed description of the technical activities of the IC.

- The database management systems developed to support BCE research used the relational database product Oracle (Version 9) as the primary software platform for data entry, validation, storage, retrieval, modification, and security. Oracle was selected as the relational database management system (RDBMS) given FCCC's long experience (since 1979) with this RDBMS. The Oracle database resides on a Sun Solaris8 Enterprise 5500 server. The machine has 3Gb of memory, 2 Ultrasparc II CPU's and 300Gb of data storage using fiberchannel disks on a Sun T3 RAID controller. Redundant network cards, system disks and power supplies are installed on the system to reduce system downtime. For security reasons, users are not allowed to log directly into the system at the operating system level. The applications server used for this project is a Sun Microsystems Sunfire 280R Server. This system is capable of serving Oracle forms, server-side Java applications, PHP or PERL-CGI scripts. These systems are backed up on a daily basis (Veritas Netbackup) and reside in a high-security machine room. The FCCC P30-supported High Performance Workstation Facility maintains all of these systems.
- Creation of 'user-friendly' data entry/retrieval interfaces was an important component in reaching our goals. A different web-based electronic data entry/retrieval form was created for each data structure using Oracle*FORMS or J2EE server-side technologies. In either case, the resulting electronic screens were designed as replicates of the forms on which the data are first collected (see examples in appendix I). During data entry, validation occurred in up to six ways: (1) *Variable Type Checks* - each variable was defined as a specific data type (e.g., date, integer, character, etc.) as determined by the data dictionaries. Entry of a variable into a field was restricted to a specific type (e.g., character data may not be entered into a numeric field); (2) *Range Checks* - For numeric and date variables, ranges were set; any value outside the range defined in the data dictionary was rejected, and the error was flagged; (3) *List of Possible Values Checks* - When character or numeric data were entered, the value was checked against a list of acceptable values; (4) *Internal Logical Consistency Checks* - Data quality was further ensured by making certain that mutually dependent fields contain logically appropriate data (e.g., study entry date must occur after birth date); (5) *Data Completeness Checks* - The data was inspected to ensure that all required data were included (e.g., identification data). Additionally, given the relational nature of the proposed database, the data were inspected to ensure that when record(s) exist in a detail table, a matching record exists in the master table; (6) *Duplicate Record Checks* - The data were inspected to prevent the entry of duplicate records into the database.
- Upon request, and with appropriate approval, data files were produced and passed to the project statisticians and investigators. To allow for analyses that utilized information obtained from different sources or studies, these extracted data files could contain information from a variety of tables and sources. IC staff were available to perform statistical programming tasks under the direction of the project investigators or biostatisticians. The majority of these analyses were conducted using the SAS and SPSS statistical packages.

- Most Human Subjects issues are covered under each of the individual projects. However, in order to preserve privacy, a series of security procedures were undertaken. Through the use of the username/password security measures available within the operating system (UNIX) and the relational database management system software, restrictions were applied to each user commensurate with their needs to access the data. All FCCC computers used for storing the information maintained by the IC are protected from inappropriate outside access by the FCCC firewall. Any off-campus internet based data communications were encrypted with 128 bit SSL (Secure Socket Layer) and use X.509 security certificates to provide additional protection

Details of the IC services provided to the four BCE research projects are provided below.

Project I: Understanding Breast Cancer Risk Assessment and Screening Behavior among the Underserved

The overall goal of Project I is to identify and assess barriers and facilitators to participation in breast cancer risk assessment and adherence to breast cancer screening recommendations among African American women.

Core staff collaborated with project investigators and staff to refine and finalize the data flow and telephone data collection instruments. Core staff used a case tool (PowerDesigner 6.1.0) to model the database, represent the physical organization of data in a graphic format, generate database creation and modification scripts, define referential integrity triggers and constraints, generate extended attributes, and generate a data dictionary. Core staff designed and developed a Computer Assisted Telephone Interview (CATI) system to meet the specific needs of this study. The application calculates each participant's estimated risk of developing breast cancer through an interface with a FORTRAN implementation of Dr. Mitchell Gail's algorithm (Gail et al, 1989). A graphical user interface (GUI) system for displaying and scheduling follow-up phone interviews was also developed. The relational database system built for this study included 22 database tables and 13 separate data entry/retrieval interfaces. Views of the database were created and data dictionaries prepared to facilitate analyses by investigators and biostatisticians. Additionally, core staff performed statistical computing tasks and developed accrual reports.

Project II: Project II: Cancer – A Teachable Moment within the Family: From Concept to Community

The goal of this study is to test the effectiveness of a tailored intervention to increase participation rates in a FCCC high-risk breast cancer program. A secondary aim is to explore the effect of the intervention on breast cancer screening practices.

Core staff collaborated with project investigators and research staff to refine and finalize the data flow and hardcopy data collection instruments. Additionally, core staff designed and developed a data entry application to meet the specific needs of this study. This system maintains all of the information collected in this study including: health history, clinical, epidemiologic, socio-demographic, and psychosocial data. In addition, this database contains cancer and vital status

data on relatives of individuals recruited into the study. The software also generated multigenerational pedigrees from the union of family histories provided by two or more distinct study subjects in the same family. The family data could be updated from follow-up information to include deaths or new cancers reported for study subjects, previously listed family members, as well as new births. The system randomized participants to study arm based on strata defined by the participant's MBSS score, her family history of cancer and age at last mammogram. Tailored and control scripts were automatically generated at time of randomization using Oracle Reports. Core staff also developed: a ticker/reminder system that notified appropriate staff when a 12-month follow-up phone survey was due; report generation software that produced printed materials (dependant upon study arm assignment) with accompanying cover letters; and database views that were used by project staff to display information about study participation. The relational database system built for this study included 26 database tables and 14 separate data entry/retrieval interfaces. All software underwent thorough testing by demonstrating that each function was operational and performed according to specification. Core staff performed statistical computing tasks, developed accrual reports and provided SAS datasets to investigators and biostatisticians. IC staff also performed data entry for this project.

Project III: Facilitating Re-entry Following Treatment for Primary Breast Cancer

The primary objective of this study is to develop and evaluate a C-SHIP guided Cognitive-Affective Processing (CAP) intervention to facilitate psychosocial adjustment at re-entry, following adjuvant treatment for primary breast cancer.

Core staff collaborated with project investigators and research staff to refine and finalize the data flow and hardcopy data collection instruments for participant enrollment and the storage of data from the participant's baseline and follow-up assessments. Core software engineers designed and developed a database system consisting of 28 database tables and 24 data entry/retrieval forms to meet the specific needs of this study. All software underwent thorough testing, before release to production, by demonstrating that each function was operational and performed according to specification. Core staff created database views and prepared data dictionaries to facilitate analyses by investigators and study biostatisticians. IC staff also performed data entry for this project.

Project IV: Impact of a Communication Skills versus a Supportive Therapy Intervention for Women with Metastatic Breast Cancer

The goal of this study is to compare a cognitive-behavioral intervention (with a communication and support training focus) to a supportive therapy intervention on the quality of life of women with metastatic breast cancer. A secondary aim is to explore moderating effects of individual dispositional factors and mediating effects of support-related variables on the impact of the intervention strategies.

Core staff collaborated with project investigators and research staff to refine and finalize the data flow and hardcopy data collection instruments. PowerDesigner was used to model the database, represent the physical organization of data in a graphic format, generate database creation and modification scripts, define referential integrity triggers and constraints, and generate a data

dictionary. This database system contained 33 database tables. Thirty six separate electronic data entry/retrieval forms were included in the system. A system for the scheduling of follow-up visits and electronic screens displaying subjects due for follow-up was also developed. As with each of the projects, all software was thorough testing by demonstrating that each function was operational and performed according to specification. Core staff prepared data dictionaries and generated views of the database to facilitate analyses by investigators and study biostatisticians using SAS, SPSS and STATA. Core staff performed statistical computing tasks and developed accrual reports. IC staff also performed data entry for this project.

In total, data from 338 research participants is stored in these information systems (see Table 1).

Table 1: Accrual by Project					
		Project			
		1	2	3	4
Race					
	Black/African American	58 (100%)	11 (7%)	1 (2%)	6 (11%)
	White	0 (0%)	144 (87%)	41 (68%)	47 (87%)
	Asian	0 (0%)	2 (1%)	0 (0%)	0 (0%)
	Other	0 (0%)	1 (1%)	1 (2%)	0 (0%)
	More Than One Race	0 (0%)	0 (0%)	2 (3%)	0 (0%)
	Unknown	0 (0%)	8 (5%)	15 (25%)	1 (2%)
Ethnicity					
	Hispanic/Latino	0 (0%)	3 (2%)	0 (0%)	1 (2%)
	Unknown	58 (100%)	163 (98%)	60 (100%)	53 (98%)
Age					
	20-29	9 (16%)	13 (8%)	0 (0%)	0 (0%)
	30-39	14 (24%)	56 (34%)	4 (7%)	3 (6%)
	40-49	12 (21%)	65 (39%)	13 (22%)	14 (26%)
	50-59	12 (21%)	20 (12%)	16 (27%)	13 (24%)
	60-69	10 (17%)	11 (7%)	8 (13%)	16 (30%)
	70-79	0 (0%)	1 (1%)	4 (7%)	7 (13%)
	80-89	0 (0%)	0 (0%)	0 (0%)	1 (2%)
	Unknown	1 (.02%)	0 (0%)	15 (25%)	0 (0%)
TOTAL		58	166	60	54

KEY RESEARCH ACCOMPLISHMENTS

- Core staff attended and participated in scheduled BCE meetings.
- Core staff collaborated with Project Investigators and research staff to refine the data flow and hardcopy data collection instruments for all four projects. Core staff developed data dictionaries based on study requirements and data collection instruments.
- Core personnel designed and developed comprehensive information management systems targeted to the specific needs of each BCE project. These customized relational database applications were implemented by using a combination of tools that included, Java/J2EE, Oracle Forms, Oracle Reports (to produce a Tailored Telephone Interview), FORTRAN (to calculate a women's breast cancer risk, her Gail Score, during the conduct of a Computer Assisted Telephone Interview (CATI)) and Oracle database engine software. All software underwent thorough testing before release to the user community.
- Data quality assurance procedures were implemented using software-based data entry checks.
- Software for the scheduling of follow-up phone calls, and the distribution of mailed self-report questionnaires was developed for Project II.
- Software to generate reports which facilitated monitoring the progress of individual study subjects and study accrual was developed for each project.
- Security measures for accessing data were implemented by utilizing role based authentication and authorization. Fox Chase Cancer Center uses a Lightweight Directory Access Protocol (LDAP) directory service, implementing a subset of the InteOrgperson/EduPerson V2.0 schema, to provide a robust, extensible, and well-controlled common authentication mechanism. Restrictions are applied to each user commensurate with their needs to access the data (roles) at the application and database level.
- IC staff provided data entry and quality assurance for Projects II, III and IV.
- IC staff provided statistical computing support to all four BCE studies.
- All FCCC computers used for storing the information were protected from inappropriate outside access by the FCCC firewall.

REPORTABLE OUTCOMES AND BIBLIOGRAPHY OF PUBLICATIONS

- none

CONCLUSION

This Core served as a resource for the Center of Excellence as a whole and will maintain a valuable source of data for current and future studies. By centralizing these services into an Informatics Core, we were able to manage and coordinate the collection, storage, and distribution of a large amount of highly valuable data. In addition, substantial efficiencies and economies of scale were achieved by this coordinated approach. Subject to Informed Consent, the information contained in the data repository was available to all investigators in the Center of Excellence. By providing access to the data for all participants, sharing technical capabilities and ensuring the quality of the data, this core has not only facilitated achievement of the aims of the individual projects but also makes possible exploratory analyses beyond the stated aims of the projects.

REFERENCES

Gail, M.H., Brinton, L.A., Byar, D.P., Corle, D.K., Green, S.B., Schairer, C., et al. (1989). Projecting individualized probabilities of developing breast cancer for white females who are being examined annually. *Journal of the National Cancer Institute*, 81, 1879–86.

DOD Final Report
Blood Collection and BRCA1 and BRCA2 Mutation Testing through the Genetic Susceptibility-
Testing Laboratory Core

Dr. Suzanne M. Miller, Ph.D., Principal Investigator
Andrew K. Godwin, Ph.D., Core Director

October, 2007

Psychosocial and Behavioral Medicine Program
Division of Population Science
Fox Chase Cancer Center

INTRODUCTION

The strongest known epidemiological risk factor for breast cancer is a positive family history and studies of breast and ovarian cancer patients and their relatives consistently find statistical evidence for involvement of autosomal dominant genes. Therefore, the identification of specific genes has long been the focus of efforts to identify women at high risk. A promising approach for reducing the high incidence and mortality associated with breast cancer lies in the early detection of women at high risk. These women, once identified, can be targeted for more aggressive preventative programs and tailored interventions to help cope with their increased risk of developing cancer. As a result of the cloning of the two most prominent breast-ovarian cancer susceptibility genes, *BRCA1* and *BRCA2*, it is now possible to screen women from high-risk families for germ-line mutations. This Core was created to support Project 2, “Cancer-A Teachable Moment Within the Family; From Concept to Community” and Project 3, “Facilitating Re-entry following Treatment for Primary Breast Cancer”. Project 2 proposes to test the efficacy of a health communication message personalized to a set of demographic, clinical, and psychosocial factors and timed to capitalize on the heightened awareness of breast cancer risk attributed to the recent diagnosis in a first-degree relative (FDR). The purpose of the health communication message is to encourage that these at-risk women participate in the Family Risk Assessment Program at FCCC or the Network Hospitals in order to receive personalized breast cancer risk information provided to the participants. *BRCA1* and *BRCA2* mutation analysis is offered to those who have familial patterns of breast cancer indicative of a possible involvement of a disease-associated germline mutation. Similarly, Project 3 proposes to provide tailored communications. However, the communications are provided to breast cancer patients actively undergoing treatment. The communications are designed to enhance adjustment, quality of life, and adherence to recommended follow-up regimens during survivorship. Participants are extended an offer to participate in FRAP to receive familial risk information. Eligible participants, based again on family history of breast cancer, are offered *BRCA1* and *BRCA2* mutation analysis.

Specifically, the aims of the Core are as follows:

Aim 1: To collect and bank blood samples from women with breast cancer or unaffected women with a family history of breast cancer as part of Projects 2 and 3.

Aim 2: To evaluate constitutive DNA from individuals participating in the Projects 2 and 3 for mutations in *BRCA1* and *BRCA2*.

We have an extensive history of collecting and banking biospecimens from women at an increased risk for breast and/or ovarian cancer at the Fox Chase Cancer Center. During the past year we collected and processed blood samples from hundreds of FRAP participants and have screened for germline mutations in *BRCA1* and *BRCA2*. We have improved our methods to identify germline mutations as well as to assess the impact of these mutations on cancer risk. To date, we have identified more than **600** *BRCA1* and/or *BRCA2* mutation carriers (including **91** unique deleterious mutations) using our EMD approach. The personnel and methodology are in

place to handle and screen the BCE samples as they are obtained. We attend the monthly BCE meetings to discuss recruitment and to up date the progress we have made in our genetic testing.

BODY

The strongest known epidemiologic risk factor for breast cancer is a positive family history and studies of breast and ovarian cancer patients and their relatives consistently find statistical evidence for involvement of autosomal dominant genes. Therefore, the identification of specific genes has long been the focus of efforts to identify women at high risk. A promising approach for reducing the high incidence and mortality associated with breast cancer lies in the early detection of women at high risk. These women, once identified, can be targeted for more aggressive preventative programs and tailored interventions to help cope with increased risk. As a result of the cloning of the two most prominent breast-ovarian cancer susceptibility genes, *BRCA1* and *BRCA2*, it is now possible to screen women from high-risk families for germ-line mutations. We developed this Core base on our previous experiences in effectively collecting thousands of blood samples from research participants with family histories of breast and/or ovarian cancer, and in screening for mutations in *BRCA1*, *BRCA2*, and other candidate breast cancer susceptibility genes. This Core supports Projects 2 and 3 (as well as the other Project in the BCE if the need arises), by providing a highly accurate and cost-effective means for testing eligible participants for mutations in the two most prominent breast cancer susceptibility genes, *BRCA1* and *BRCA2*.

KEY RESEARCH ACCOMPLISHMENTS

- Improved the ability to detect *BRCA1* and *BRCA2* mutations in genomic DNA.
- Reduced the cost of full *BRCA1* and *BRCA2* mutation analyses to a third of the cost of commercial testing without loss of sensitivity.
- Created *BRCA1* and *BRCA2* exon chips for detection of genomic rearrangements in these two genes.
- Included mutation detection technology for large deletions/insertions in *BRCA1*, an extension of PCR based mutation detection; included in our *BRCA1* and *BRCA2* full screen will be testing for the panel of 5 *BRCA1* deletions/insertions currently performed by the primary *BRCA1/BRCA2* clinical testing agent.
- Further reduced cost for *BRCA1* and *BRCA2* mutation analysis by enzyme mutation detection by performing our own DNA sequencing.
- Identified 74 novel polymorphisms common to ethnic populations; identified 7 novel frameshift mutaitons, 4 novel intronic variants, and 33 novel variants of uncertain significance in our ethnic populations.

- Developed a PCR based method to evaluate RNA for splicing changes in those specimens where intronic alterations have been identified.

REPORTABLE OUTCOMES AND BIBLIOGRAPHY OF PUBLICATIONS

• Abstracts

*=supported by DAMD17-01-1-0238 (“Tailored Communications to Enhance Adaptation Across the breast Cancer Spectrum”)

**=Demonstrates refinement and application of our methods to detect germline mutations in high-risk individuals.

• Presentations

*Neuhausen, S.L., Lynch, H.T., Weber, B.L., Garber, J.E., Daly, M.B., Godwin, A.K., Wagner, T., Nathanson, K., Farnham, J., Narod, S.A., & Rebbeck, T.R. (2003). Modification of *BRCA1*- and *BRCA2*-associated breast and ovarian cancer risk by *RAD51*. *Proceedings of American Association of Cancer Research*, 44, 574.

• Publications

**Wagner, T., Costalas, J., Itzen, M., Malick, J., Babb, J.S., Bove, B., Godwin, A.K., & Daly M.B. (2003). Communication of *BRCA1* and *BRCA2* results to at-risk relatives: A cancer risk assessment program's experience. *American Journal of Medical Genetics*, 119C, 11-18.

CONCLUSION

The work that we have performed during the first six years of this application has served to improve our ability to detect mutations in the two prominent breast cancer susceptibility genes, *BRCA1* and *BRCA2*. We have published our mutation detection method and have shown that it is comparable if not superior to commercial methods at a significantly lower cost. We have also developed a method to detect large genomic rearrangements in *BRCA1* and *BRCA2* that elude detection when using PCR-based approaches to search for mutations. We are also developing in our testing regimen a PCR based method for detecting large insertions/deletions in *BRCA1* and *BRCA2*. Overall, we are in optimal position to appropriately analyze any and all BCE samples once they become available through Projects 2 and 3. Furthermore, we will be able to process more samples than originally proposed due to our technical improvements and ability to automate the method.

REFERENCES

None

LIST OF PERSONNEL

Miller, Suzanne	Principal Investigator
Apledorn, Shirley	Secretary II
Armstrong, Brock	Scientific Technician II
Armstrong, Cary	Genetics Counselor I
Atchison, Margaret	Health Educator II
Babb, James	Senior Research Biostatistician
Barabin, Diane	Health Educator
Bove, Betsy	Research Associate
Brower, Lisa	Research Study Assistant
Burden, Jenny	Health Educator II
Butler, Daniel	Research Study Assistant
Buzaglo, Joanne	Senior Scientific Assistant
Cardone, Candice	Research Study Assistant
Cherry, Carol	Project Manager
Costalas, Josephine	Genetics Counselor
Crozier, Lorraine	Secretary II
Daly, Mary	Senior Member
DeVirgiliis, Jennifer	Research Study Assistant
Didura, Halyna	Data Entry Clerk
Diefenbach, Michael	Associate Member
Dorsey, Jenevie	Project Manager
Egleston, Brian	Assistant Member
Eisenberg, Jessica	Student Assistant
Enchauteguis, Irasema	Research Data Coordinator
Fleisher, Linda	Senior Director Outreach
Floyd, Briana	Health Educator
Gaymon, Avery	Project Manager
Geary, Shannon	Health Educator
Gillespie, Kathleen	Research Study Assistant
Ginsberg, Barbara	Assistant Director
Glenn, Melanie	Project Manager
Hamrick, Natalie	Postdoc Associate
Hill, Douglas	Senior Project Manager
Hinton, Natasha	Project Manager
Howze, Nina	Health Educator
Kandadai, Venk	Student Intern
Kimenour, James	Unit Aide
Klein, Margaret	Health Educator II
LaMonica, Stephen	Project Manager
Leber, Elva	Health Educator II
LeMaitre, MK	Senior Project Manager
Litwin, Samuel	Member
Manne, Sharon	Senior Member
Marks, Jaime	Health Educator II

Michael, Julie	Data Coordinator
Miller, Suzanne	Senior Member
Minogue, Kristie	Health Educator
Montgomery, Susan	Project Manager
Mosley, Nimanee	Health Educator II
Neith, Katie	Research Study Assistant
O'Connell Janice	Genetics Counselor II
Pearson, Dara	Research Study Assistant
Peterson, Candace	Genetics Counselor
Peterson, Tinesha	Project Manager
Popa-Mabe, Melania	Health Educator II
Rodriquez, Jaime	Health Educator
Ross, Eric	Senior Director of Academic Info Systems
Ryan, Mary	Administrative Assistant
Salador, Honey	Research Study Assistant
Scarpato, John	Project Manager
Schnoll, Robert	Associate Member
Schueller, Jeanne	Project Manager
Smith, Gillian	Research Study Assistant
Stanley, Tina	Health Educator III
Stanton, Laura	Scientific Associate
Stearman, Beth	Project Manager
Tahin, Solange	Health Educator
Wai, Mara	Project Manager
Walker, Jaime	Summer Assistant II
Weber, Dorothy	Research Nurse
Wise, James	Summer Assistant II
Zheng, ShuangQi	Health Educator
Zike, Joseph	Project Manager

Appendices

- I. Informatics Core Appendix
- II. Miller S.M., & Roussi, P. (2005) Genetic Testing for Breast and Ovarian Cancer: A Review of Psychological and Behavioral Outcomes. *Hellenic Journal of Psychology*, 2, 135-58.

Informatics Core Appendix

Oracle Developer Forms Runtime

Search database for ID

Participant Registration

ID: 57468

Last Name	First Name	I	Gender	DOB	MR
FRUMP	SUZIE	F	Female	07/04/1958	99999

Title: Sister Suffix: Ed.D.

Address1	address2	Home area code	Home Phone number
1234 COMMON AVE	APT #311111	610	446-4646

City	State	Work area code	Work Phone number
ANYWHEREVILLE	PA	215	765-2222

Zip	Zip ext	Cell phone area code	Cell Phone number
12345	1111		

Email: foo@blahblah.com

Save and Continue Exit

Record: 1/1

Oracle Developer Forms Runtime - [Health and Screening History]

Health and Screening History

Page 3 of 27

ID: 57468 SUZIE F FRUMP

How many first degree relatives with breast cancer?

How old were you when you had your first period? Years old
Never had periods ☐ 1=Yes 0=No

How many times have you given birth? times (enter 0 if you have never given birth)

What was your age at first live birth of a child? Years old (leave blank if you have never given birth)

Have you ever had a hysterectomy (removal of the uterus or womb)? ☐ 1=Yes 0=No

Have you had your ovaries removed? ☐ 1=Yes 0=No

To Exit - Ctrl Q

Record: 1/1

Oracle Developer Forms Runtime - [Health and Screening History]

Health and Screening History Page 6 of 27

ID: 57468 SUZIE P FRUMP

33. How many breast biopsies (breast tissue removed by a surgery) have you had in the past? (Do not enter anything if there is no breast biopsy)

If you have had a breast biopsy please fill out the following table. Please start with the most recent breast biopsy and work back. If you cannot remember all of the information it is OK.

	Date of biopsy, Most recent first		Results
Biopsy 1	02/2002 (MM/YY)	Cancer LCIS Atypical Hyperplasia DCIS	0 0 0 0 1-Yes 0-No -1-Don't Know
Biopsy2	(MM/YY)	Cancer LCIS Atypical Hyperplasia DCIS	
Biopsy3	(MM/YY)	Cancer LCIS Atypical Hyperplasia DCIS	

Gail Model Score: 1.6094

hit ENTER

Forms

The gail score is: 1.6094

start | Send Items - Mo... | http://www.aca... | Windows Exp... | screenPhoto.doc - Microsoft Word | Oracle Developer... | My Computer | 9:52 AM

Oracle Developer Forms Runtime

WINDOW1

Adverse Events

Study ID: 57468 Form Comp. date: 09/25/2007 MR#: 99999

Adverse Event/Drug Reaction: LOV=F9

Grade Participant Outcome:

Study Drug Relationship: Serious:

Action Taken: Reported to: DSMB

Treatment Required: IRB

RRC

NIH

Save (S), Review (R) or Abort (A):

Find

Abdominal pain
Agitation
Alertness
Backout
Bronchitis
CNSO
Calmness
Coldness of hands and feet
Constipation
Coughing
Death
Dehydration
Diabetes
Diarrhea
Difficulty breathing
Dizziness
Dry mouth
Dry painful eyes
Elevated blood pressure, hypertension
Esophageal burning
Excessive saliva
Exhaustion
Fainting
Fever

Find OK Cancel

Choices in list: 55
Record: 1/1 List of Values

Oracle Developer Forms Runtime - [ped_fam_dx]

PEDIGREE FAMILY DIAGNOSIS

ID: 64738 FamId: 3671 First Name: JANE MI: M Last Name: DOE

Pedigree Review Date: 09/26/2007

Mat Class: 2 Mat Type: Mat Religion: Mat Country: **F9 for a List of Values**

Pat Class: Pat Type: Pat Religion: Pat Country:

Pat Religion Other:

Mat Religion Other:

Is all the information entered above correct? ☐

**To Exit - Ctrl+q
Previous Field - Shift Tab**

Find: %

116 AMSTERDAM/VARIOUS
13 BCC
43 BLADDER
105 BLADDER/COLON
107 BLADDER/VARIOUS
56 BONE
63 BRAIN
65 BRAIN/NOSE
27 BRICAL
18 BRICAZ
1 BREAST
51 BREAST/BRICAZ
7 BREAST/BCC
17 BREAST/BRICAZ
20 BREAST/COLON
49 BREAST/COLON/LUNG
113 BREAST/COLON/VARIOUS
81 BREAST/HEAD/NOSE
47 BREAST/HEMATOLOGIC
41 BREAST/HPCC
92 BREAST/LIVER/NOSE/COLON/VARIOUS
95 BREAST/LIVER/NOSE

Find OK Cancel

Chosen in list: 111
Record: 1/1 List of Values

Oracle Developer Forms Runtime - [BCE2]

BCE2 Randomization

Enter in ID: 64738 JANE M DOE 3671

Family History: intermediate risk

Screening Behaviors: Non-Compliant

Monitor: Low Monitor

Is the above information correct? ☐ Enter in Y or N

Subject's study group assignment:

Please enter your initials:

0 = Control 1 = Intervention

**To Exit - Ctrl+q
Previous Field - Shift Tab**

Enter a "Y" or "N"
Record: 1/1

RIES - Mozilla Firefox

File Edit View History Bookmarks Tools Help

https://studies-dev.fccc.edu/instruments/getPiles.do?surveyResponseId=2123

Participant Details RIES

RIES

Instructions: Below is a list of comments made by people after various life events. We are interested in knowing how you feel about your oral health.

Please answer the following questions for the past week, including today. Please circle a number to indicate how frequently these comments are true for you in response to your health.

If none of these responses occurred, please circle "not at all." There is no right or wrong answer, so choose the most accurate answer for YOU -- not what you think "most people" do.

	Not at all	Rarely	Sometimes	Often
1. I thought about it when I didn't mean to.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. I avoided letting myself get upset when I thought about it or was reminded of it.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. I tried to remove it from memory.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4. I had trouble falling asleep or staying asleep because of pictures or thoughts about it that came into my mind.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5. I had waves of strong feelings about it.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
6. I had dreams about it.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
7. I stayed away from reminders about it.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
8. I felt as if it hadn't happened or it wasn't real.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
9. I tried not to talk about it.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Done studies-dev.fccc.edu

Oracle Developer Forms Runtime - [BCE4]

Therapist - TSR

ID #: H004 Session: 1 Date: 06/02/2004

How do you feel about the session which you have just completed. This Session was: 8

My patient seemed to feel:

1. Confident <input type="radio"/>	9. Tearful <input type="radio"/>	17. Depressed <input type="radio"/>	25. Discouraged <input type="radio"/>
2. Embarrassed <input type="radio"/>	10. Close <input type="radio"/>	18. Affectionate <input type="radio"/>	26. Accepted <input type="radio"/>
3. Relaxed <input type="radio"/>	11. Impatient <input type="radio"/>	19. Serious <input type="radio"/>	27. Cautious <input type="radio"/>
4. Withdrawn <input type="radio"/>	12. Guilty <input type="radio"/>	20. Anxious <input type="radio"/>	28. Frustrated <input type="radio"/>
5. Helpless <input type="radio"/>	13. Strange <input type="radio"/>	21. Angry <input type="radio"/>	29. Hopeful <input type="radio"/>
6. Determined <input type="radio"/>	14. Inadequate <input type="radio"/>	22. Pleased <input type="radio"/>	30. Tired <input type="radio"/>
7. Grateful <input type="radio"/>	15. Likeable <input type="radio"/>	23. Inhibited <input type="radio"/>	31. Ill <input type="radio"/>
8. Relieved <input type="radio"/>	16. Hurt <input type="radio"/>	24. Confused <input type="radio"/>	32. Sexually Att. <input type="radio"/>

Other 33. 34. Exit=Ctrl+Q

1=Perfect 2=Excellent 3=Very good 4=Pretty good 5=Fair 6=Pretty poor 7=Very poor
Record 1/1

Oracle Developer Forms Runtime - [WINDOW1]

Client -TSR

ID #: H004 Session: 1 Date: 06/02/2004

How do you feel about the session which you have just completed.

DURING THIS SESSION I FELT:

1. Confident	4	9. Tearful	1	17. Depressed	0	25. Discouraged	0
2. Embarrassed	0	10. Close	2	18. Affectionate	3	26. Accepted	3
3. Relaxed	4	11. Impatient	0	19. Serious	3	27. Cautious	0
4. Withdrawn	0	12. Guilty	0	20. Anxious	0	28. Frustrated	0
5. Helpless	0	13. Strange	0	21. Angry	0	29. Hopeful	3
6. Determined	0	14. Inadequate	0	22. Pleased	3	30. Tired	0
7. Grateful	3	15. Likeable	3	23. Inhibited	0	31. Ill	0
8. Relieved	3	16. Hurt	0	24. Confused	0	32. Sexually Att.	0

Other 33.

1=Perfect 2=Excellent 3=Very good 4=Pretty good 5=Fair 6=Pretty poor 7=Very poor
Record 1/1

Oracle Developer Forms Runtime - [WINDOW1]

FGCC Tickler System

Study ID	First Name	Last Name	Due Date	Event	Resolved
H004	JANE	SMITH	05-APR-2005	Followup 2 Letter	<input type="checkbox"/>
I041	JOAN	DOE	26-JUL-2005	Followup 2 Letter	<input type="checkbox"/>
					<input type="checkbox"/>
					<input type="checkbox"/>
					<input type="checkbox"/>
					<input type="checkbox"/>
					<input type="checkbox"/>
					<input type="checkbox"/>
					<input type="checkbox"/>
					<input type="checkbox"/>

Window before Due Date (in days): 14

Record 1/2

GENETIC TESTING FOR BREAST AND OVARIAN CANCER: A REVIEW OF PSYCHOLOGICAL AND BEHAVIORAL OUTCOMES

Pagona Roussi & Suzanne M. Miller

*Aristotle University of Thessaloniki, Greece & Fox Chase Cancer Center,
Philadelphia, USA*

Abstract: In this paper, we review the literature on genetic testing and management uptake in women at increased risk for breast and ovarian cancer, from a theory-guided perspective. In the first section, basic information regarding hereditary breast and ovarian cancer is presented and issues raised by the availability of genetic testing are briefly discussed. The cognitive-affective health information processing model, which is used to integrate the findings in the existing literature, is introduced in the second section. Then, we review the psychological outcomes of receiving and communicating a genetic test result (third and fourth sections) and the impact of genetic testing on risk reduction and early detection behaviors (fifth section). In the final section, we provide an integrative overview of the literature, discuss the limitations of the existing research and delineate recommendations for future research.

Key words: Behavioral outcomes, Genetic testing, Psychological outcomes.

Recent technological advances have provided individuals with the unprecedented opportunity to undergo testing to discover whether or not they are carriers of genes that have been associated with various diseases, such as Huntington's disease and, more recently, breast and ovarian cancer (Burke et al., 1997; Leavitt, Wellington, & Hayden, 1999). Hereditary breast and ovarian cancer has been associated with alterations in the BRCA1 and

Note: This article was supported in part by NIH grants R01 CA104979 and P30 CA06927, and Department of Defense grant DAMD 17-01-01-1-0238.

Address: Pagona Roussi, School of Psychology, Aristotle University of Thessaloniki, 541 24 Thessaloniki, Greece. E-mail: roussi@psy.auth.gr

Address: Suzanne Miller, Fox Chase Cancer Center, 333 Cottman Avenue, Suite P1096, Philadelphia, PA 19111, USA. E-mail: SM_Miller@fccc.edu

BRCA2 genes. *BRCA1* (chromosome 17) and *BRCA2* (chromosome 13) mutations are inherited in an autosomal dominant fashion¹. These genes are likely to function in tumor suppression and DNA repair, although other activities within the cell cycle have also been implicated (Welsh & King, 2001). BRCA1/2 carriers account for 84% of hereditary breast and ovarian cancers (Struwing, Hartge, & Wacholder, 1997; Whittemore, Gong, & Intyre, 1997). In addition, carriers of BRCA1 may be at an increased risk for colorectal cancer (Ford, Easton, Bishop, Norad, & Goldgar, 1994), whereas carriers of BRCA2 may be at an increased risk for prostate and pancreatic cancer (Gayther et al., 1997).

Participants in breast and ovarian cancer genetic testing receive a positive, a negative or an uninformative test result (Daly, 1999). A positive test result is given when a known deleterious mutation is detected. It is estimated that women who test positive have a 15% to 60% lifetime risk of developing ovarian cancer and a 55% lifetime risk of developing breast cancer (Struwing et al., 1997; Whittemore et al., 1997). A negative test result is given when a deleterious mutation is not detected in the person, but has been detected in the family. In both of these cases, uncertainty about genetic risk status is significantly, although not completely, reduced. A positive test result does not mean that one will definitely get the disease and women with a true negative test result, depending on their family history of cancer, at best have the same risk as the general population. Most commonly, women receive an uninformative test result which is given: (1) when a deleterious mutation is not detected in the participant and a mutation in the family has not been identified as yet (indeterminate), or (2) when a mutation whose significance is unknown has been detected (inconclusive) (Daly, 1999). As the information above illustrates, there is uncertainty connected with all outcomes, to some extent. Thus, the information that is provided is complex and probabilistic, making uncertainty an integral part of the BRCA1/2 testing process.

The ultimate goal of providing genetic testing services for cancer is the hope that the identification of relevant genes will allow for recommendations about available risk-reduction behaviors and/or increased screening for early detection of the disease (Daly, 1999). Unlike testing for other diseases (such

¹ A single, abnormal gene on one of the autosomal chromosomes (one of the first 22 "non-sex" chromosomes) from either parent can cause certain diseases. Only one parent (either one) must have an abnormal gene in order for the child to inherit the disease.

as Huntington's), there is increasing evidence that women testing positive for BRCA1/2 have options that can help them detect cancer early and/or reduce the risk of incurring cancer in the first place. However, there are currently no fully accepted guidelines for women on what courses of action to follow (Daly, 1999). Hence, women are required to process new information and to make decisions in the context of uncertainty and unfamiliar outcomes. Women receiving positive test results are generally counseled about their follow-up options, including preventive surgery (after childbearing is over), chemoprevention, and/or increased screening. Preventive surgery refers to bilateral prophylactic mastectomy and to bilateral prophylactic oophorectomy, that is, removal of either breasts or ovaries. Chemoprevention refers to the use of hormone-based agents, such as tamoxifen, in order to reduce the risk for breast cancer. These decisions are particularly problematic for those women who receive an uninformative test result, who are counseled to make clinical decisions on the basis of the strength of the family history, and not necessarily on the test result (Daly, 1999).

In order to benefit from feedback provided in genetic testing, and to engage in informed decisions regarding follow-up prevention behaviors, women must be willing to take advantage of its availability. A number of studies have been conducted to determine the actual rates of genetic testing uptake among at-risk women. Descriptive studies have shown that rates of genetic testing among high-risk women are high, ranging from 55% to 93% (Biesecker et al., 2000; Meijers-Heijboer et al., 2000; Smith, West, Croyle, & Botkin, 1999). For average risk populations, the rates range between 18% and 58% (Hartenbach et al., 2002; Peterson, Milliron, Lewis, Goold, & Merajver, 2002). Most sites that offer genetic testing try to prepare women for the process and the impact of the disclosure of the test result. Standard counseling approaches typically involve the provision of personalized information regarding risk, presentation of the benefits, limitations, and risks of genetic testing, and information regarding the meaning of the result and about the options available for early detection and risk-reduction. Usually, counseling takes place both before genetic testing and after feedback of the test result and has as goals: (1) to educate and inform women of the genetic condition, (2) to provide support and help them cope, and (3) to facilitate informed decision-making (Wang, Gonzalez, & Merajver, 2004).

Genetic testing raises a series of theoretically relevant psychosocial issues. This paper reviews findings regarding three issues: (1) the psychological impact of genetic testing on the individual, (2) issues related to the commu-

nication of test results to the family, and (3) the impact of genetic testing on the uptake of risk reduction and early detection (screening) behaviors. Before reviewing the existing literature on these issues, we present the cognitive-affective health information processing model, which will be used as the theoretical framework to conceptualize available research.

THE COGNITIVE-AFFECTIVE HEALTH INFORMATION PROCESSING MODEL

The cognitive-affective health information processing (C-SHIP) model (Miller, Shoda, & Hurley, 1996) highlights the role of five main cognitive-affective processing units—encoding beliefs and expectancies, values and goals, affects, and self-regulatory competencies and skills. These units interact in a complex and personal, albeit predictable, way for each individual facing a health threat (Miller et al., 1996). In the health context, health-relevant encoding, such as perceived risk, refers to the way in which health-relevant information is encoded and integrated into the person's available knowledge system (Miller & Diefenbach, 1998). Health-relevant beliefs and expectancies refer to the individual's beliefs about the health-threat (e.g., the identity of an illness and cause of the illness) and outcome and efficacy expectancies (e.g., outcomes of prophylactic behaviors, being confident that one is able to adhere to a medical regimen or a lifestyle change). Health-relevant values and goals refer to desires and values about health outcomes (e.g., importance of personal and family health, importance of body image). Health-relevant affects refer to emotional states activated when processing health-relevant information (e.g., cancer risk-related worries and anxieties, negative feelings about the self). Health-relevant self-regulatory competencies and skills refer to knowledge about the health problem and to the skills necessary to change this knowledge into health-protective behaviors, such as the management of both practical (e.g., financial constraints to deal effectively with a health problem) and psychological barriers (e.g., active avoidance to manage anxiety). Self-control skills are particularly important in the management of anxiety.

Based on relevant literature and findings (Bandura, 1986; Leventhal, Diefenbach, & Leventhal, 1992; Miller & Diefenbach, 1998; Miller, Fang, Manne, Engstrom, & Daly, 1999; Miller et al., 1996; Mischel & Shoda, 1995), the theory holds that individuals' encodings, expectancies about the benefits and limitations of specific cancer-related actions, health-related

values and goals, and self-regulatory competencies are combined in a dynamic way with cancer-specific emotional distress to produce a multifactorial response to a health challenge, such as genetic testing. These units interact in stable ways, so that individuals can be said to be characterized by cognitive-affective 'signatures' that determine how they respond to particular health challenges and feedback. Previous research has identified two main cognitive-affective processing styles that people use when faced with health-threats: monitoring versus blunting (Miller, 1995). The monitoring style is characterized by attending, scanning for and amplifying threat-relevant cues. The blunting style is characterized by the use of distraction to threat-relevant cues. The characteristic signature of 'monitoring' is the tendency towards high attention to health threat, as well as a pattern of heightened risk perceptions, lowered control expectations, and high health-related anxiety. This profile has been extensively studied as a marker of vulnerability to a variety of health challenges (Miller, 1995; Miller et al., 1999; Miller, Fang, Diefenbach, & Bales, 2001).

From the point of view of the C-SHIP model, the way individuals process information about their health is important to understanding their psychological and behavioral reactions to a given health-threat. Nonetheless, when encountering a health-threatening situation, people are less likely to be aware of their own cognitions and affects, thus making it difficult to self-manage their emotional reactions in a psychologically preventive fashion. In the following sections, we will review the three issues raised in the previous section, using the C-SHIP model as the theoretical basis.

PSYCHOLOGICAL IMPACT OF GENETIC TESTING

The main goal of the studies that examine the impact of genetic testing on distress is to understand both the short- and long-term psychological impact of the test result, as well as the moderating impact of medical and personal variables. In general, initial concerns that a positive test result leads to high levels of psychological distress appear to be unfounded. Women generally experience a drop in distress when they receive a negative result (Croyle, Smith, Botkin, Baty, & Nash, 1997; Lerman et al., 1996). Women who test positive do not show the same immediate drop in distress, but one month post-test result they do not show an increase either (Croyle et al., 1997; Lerman et al., 1996). The fact that genetic testing is not associated with elevated levels of distress suggests that the negative impact of a positive test

result is, in part at least, mitigated by the decrease in uncertainty that the test result provides (Wang & Miller, *in press*). In a study based on in-depth interviews with affected women, many carriers said that they were relieved to have the etiology of their family history confirmed and to have the information needed to reduce their uncertainty regarding their carrier status (Hallowell, Foster, Ardern-Jones, Eeles, Murday, & Watson, 2002). However, in the same study, carriers talked about the increase in anxiety regarding their own risk of developing another form of cancer, their worry about the increased risks of developing cancer for their relatives, and their anxiety about disclosing their result to relatives. All of these indicate that the receipt of genetic test results is associated with some forms of conflicting psychological reactions.

For the majority of women, then, negative psychological reactions are not a significant concern. Nonetheless, there is a subset of women who are vulnerable to the receipt of a positive test result (Dorval et al., 2000; Schwartz, Peshkin, Hughes, Main, Isaacs, & Lerman, 2002; Wood, Mullineaux, Rahm, Fairclough, & Wenzel, 2000), indicating that individual variables may moderate the relationship between test result and adjustment. Specifically, certain types of background factors—whether or not one is affected with cancer and time elapsed since diagnosis—have been associated with a differential response to genetic test result. For example, among affected women, genetic test result does not appear to differentially predict cancer-specific distress, six months post-result, among carriers and non-carriers, but it does among unaffected women (Schwartz et al., 2002). Among affected women, distress is highest for those who were both recently diagnosed and who have tested positive for a genetic mutation (Wood et al., 2000). Presumably, the experience of living with a diagnosis of cancer over time facilitates the development of coping strategies, which can be activated to manage the distress of a positive test result. In contrast, unaffected women, as well as women recently diagnosed with disease, have not yet processed, prepared for, or developed plans for coping with this type of information.

The importance of encoding (self-construals), values, and goals on psychological adjustment to a positive test result is also evident when the familial context is taken into account. Female BRCA1/2 carriers experience more distress when they are the first to be tested in their family, compared to relatives who participate in genetic testing later, and when their siblings test negative, compared to women whose siblings test positive (Smith et al., 1999). Male carriers whose siblings test negative experience higher distress

only when they are tested first (Smith et al., 1999). Non-carrier males whose siblings test positive experience higher distress than non-carrier males whose siblings do not test positive, particularly when they have sisters who test positive (Smith et al., 1999). This set of findings suggests that social comparison between one's own vulnerability and that of their siblings can lead to distress. In addition, non-carriers may experience survivor guilt when their siblings test positive, possibly because the combination of a sibling's positive result with their negative result conflicts with their values.

Younger age also has been related to a negative reaction to a positive test result (Audrain, Schwartz, & Lerman, 1998), presumably because it is more likely to negatively impact the goals of young women, who are less likely to have completed child-bearing. Even among young women who have already had children, they may be more likely to feel vulnerable to a positive test result since their children are also younger. Certain expectancies also have been associated with a negative psychological reaction to genetic testing. Specifically, women who expect their reaction to a positive test result to be minimal, experience higher distress if they ultimately test positive (Dorval et al., 2000), suggesting that they may have underestimated and downplayed the psychological impact, thus leaving a discrepancy that is not easy to accommodate to.

Finally, the impact of cognitive-affective processing style can be seen from a study that explored the relationship between monitoring and psychological adjustment to genetic testing. Specifically, in a study of women undergoing genetic testing, monitoring style was associated with high anxiety while anticipating the genetic test results. Hence, there is an emotional cost, at least in the short-term, to monitoring (Tercyak et al., 2001). Following receipt of the results, test result seemed to be the determining factor, in that women with a positive test result reported higher anxiety than women who received a negative result. However, as in previous studies, this difference was the result of the reduction in anxiety among women who received a negative result rather than the result of an increase among carriers. Thus, monitoring may be most influential under ambiguous and highly threatening health challenges.

Overall, available evidence indicates that the increase in distress experienced by carriers is cancer-specific and short-lived. This finding makes sense, since genetic testing reduces uncertainty, even though does not eliminate it. However, the impact of genetic feedback on emotional response seems to be moderated by a variety of factors. Although the data are not

conclusive, cognitive factors—such as self-construals (i.e., level of perceived risk after testing), expectancies (i.e., underestimation of one's reaction to a positive test result), values (family reproduction and health), as well as self-regulatory strategies and competencies (i.e., experience with cancer)—may influence and underlie the response to risk feedback. A basic premise of the C-SHIP model is that individuals differ in the patterning of the interactions among the relevant cognitions, affects, and behaviors that are primed in the context of health threats. Consistent with the model, a prototypic example of processing type, namely monitoring, has an impact on affect under ambiguous circumstances (Tercyak et al., 2001).

Communication of genetic test result to the family

Genetic testing for breast and ovarian cancer is not just an individual experience but also has important implications for the family, such as providing genetic risk information for family members and influencing family planning (Daly et al., 2001). An important domain of emerging research focus has to do with the factors that affect the decision to communicate genetic test results to the family, the degree to which results are communicated within the family, and the impact of the communication on the individual that discloses the results.

Genetic test result seems to be an important factor in predicting whether or not the results will be communicated and to whom. Specifically, women who test positive are more likely to share their result than women with a negative or an indeterminate test result (Costalas et al., 2003; Hughes et al., 2002). This may be because of a higher need among carriers to regulate their emotional response. However, carriers are less likely to discuss their result with a child (Hughes et al., 2002), although women who are more distressed prior to testing are more likely to disclose their result to a child (Tercyak et al., 2001), presumably because of a greater difficulty to regulate their emotional response.

Exploration of the motivators of the desire to communicate genetic test result implicates women's values and goals, as well as their desire to obtain help with the self-regulation of affect and behavior. Specifically, women share the information not only to provide risk information and to encourage testing, but also to obtain emotional support and medical advice (Hughes et al., 2002). Reasons for not communicating test results include not being close to the relatives, family rifts, and not wanting to upset others, again

implicating values and goals. Affective factors also appear to be important, including the experience of guilt and anxiety both of which decrease the likelihood of communicating test results (Claes, Evers-Kiebooms, Boogaerts, Decruyenaere, Denayer, & Legius, 2003; Green, Richards, Murton, Statham, & Hallowell, 1997; Hughes et al., 2002).

Individuals generally choose to share the information with family members, mostly female relatives (Costalas et al., 2003; Green et al., 1997; Hughes et al., 2002; Lerman, Peshkin, Hughes, & Isaacs, 1998) and spouses (Claes et al., 2003, Hughes et al., 2001; Julian-Reynier et al., 2000). Among female relatives, sisters are the most likely candidates (Hughes et al., 2002; Lerman et al., 1998). For example, in one study, 90% shared their results with a spouse, 80% did so with a sister, as compared to 60% with a brother (Lerman et al., 1998). Communication with under-age children is even less likely to occur (50%).

The impact of communicating the results on the testee seems to depend on the receiver of the communication. Carriers who shared their results with a sister reported a modest decrease in their distress, but carriers who either did not disclose their result or disclosed them to young children reported an increase in distress (Lerman et al., 1998). Women who share their results with an adult probably receive support, and thus are better able to regulate their emotional response, whereas women who share their results with a child do not receive support and are more likely to experience guilt for burdening the child (Lerman et al., 1998).

To summarize, communicating one's test result to the family appears to be beneficial. Factors that impact the decision to communicate test results include a positive test result (suggesting high-perceived risk) and higher level of distress. Reasons for communication include access to social support, and hence the regulation of affect, and to medical advice, as well as the individual's values and goals in terms of believing that it is important to provide health-related information to the family.

Impact of genetic testing on risk reduction and screening behaviors

A key goal of providing genetic testing services is to allow women to make informed decisions about available management options. With BRCA1/2 testing, women who receive a positive or an uninformative result are faced with subsequent follow-up decisions, including preventive surgery (i.e., oophorectomy or mastectomy), increased screening for early detection of cancer, or a

combination of the two. Among women at increased genetic risk for breast and ovarian cancer, preventive oophorectomy and increased screening for ovarian cancer lead to a 90% to 95% reduction in ovarian cancer incidence, and a 50% reduction in new breast cancers (Kauf et al., 2002; Scheuer et al., 2002). Similarly, preventive mastectomy and increased screening for breast cancer have been associated with a 90% reduction in breast cancer (Meijers-Heijboer et al., 2001). Further, there are indications that increased screening in carriers with BRCA1/2 mutations may lead to an early diagnosis of breast and ovarian cancer (Scheuer et al., 2002), whereas chemoprevention can reduce the risk for breast cancer (Calderon-Margalit & Paltiel, 2004).

In light of these findings, the National Comprehensive Cancer Network (NCCN) guidelines for the management of hereditary susceptibility to breast and ovarian cancer recommend consideration of prophylactic surgery in women with known deleterious mutations on a case-by-case basis, with a full discussion of the risks and benefits (Daly, 1999). For breast cancer screening, the NCCN guidelines recommend, starting at age 25, annual mammogram, annual or semiannual clinical breast exam, and training in breast self-exam. For ovarian cancer, the recommendations are annual or semiannual CA-125² and transvaginal ultrasound (TVU), both starting at age 25-35, and annual pelvic exam (Daly, 1999).

Unfortunately, the information on which a decision must be made can be complex and probabilistic (see Introduction). Risk reduction decisions are particularly problematic for those women who receive an uninformative test result (Daly, 1999). Decisions regarding screening are also problematic for women concerned about their risk for ovarian cancer given the uncertain value of the currently available screening tests (CA-125 and TVU) (Daly, 1999). This is because although a number of small trials support this approach among high-risk women, the combination of a pelvic examination, CA-125 test, and TVU for the early detection of ovarian cancer has not been adequately tested in a prospective randomized trial (Jacobs, Skates, & MacDonald, 1999). It is therefore critical that women are helped to make the best decision for themselves personally, based on their risk information, evidence for the efficacy of the available risk-reduction and screening procedures, and their personal values, goals, and resources. In the next two sections,

² The CA-125 test assesses the concentration of CA-125 in the blood. CA-125 is a cancer antigen—a protein that is found in elevated levels in most ovarian cancer cells when compared to normal cells.

we present findings regarding utilization of preventive surgery and/or adherence to screening recommendations and factors that have been found to be related to the uptake of these two behavioral outcomes of genetic testing.

Risk reduction behaviors

Preventive oophorectomy. The few studies that have examined the effects of genetic testing on preventive decisions have found that genetic test result plays an important role in who undergoes preventive surgery. Further, a significant proportion of women with either a positive or an indeterminate test result does not engage in risk reduction actions. Specifically, carriers of known deleterious mutations are the most likely to use prophylactic oophorectomy, with the percentages varying from 13% to 60% (Botkin et al., 2003; Lerman et al., 2000; Meijers-Heijboer et al., 2000, 2003; Scheuer et al., 2002; Schwartz et al., 2003). Among women with indeterminate results, less than 5% choose prophylactic oophorectomy (Botkin et al., 2003; Schwartz et al., 2003). Among carriers, women whose families are affected by cancer, women who are themselves affected by cancer, and women who perceive their personal risk for cancer as high are more likely to have preventive oophorectomy (Meijers-Heijboer et al., 2000, 2003; Schwartz et al., 2003). Hence, the more vulnerable one construes oneself to be the more likely one is to undergo preventive surgery. Lack of higher education also is related to opting for surgery as a risk reduction strategy (Miller, Roussi, Rodoletz, Daly, Sherman, & Godwin, 2004b). Although this relationship needs to be further explored, it may be that the less educated women prefer a more definitive solution that gives them a higher sense of control. Finally, carriers who opt for preventive oophorectomy are older (Botkin et al., 2003; Scheuer et al., 2002; Schwartz et al., 2003), and thus are more likely to have completed child-bearing (suggesting that values and goals are important), and tend to worry more (Schwartz et al., 2003).

Preventive mastectomy. The rates for mastectomy among carriers range from zero to 61% (Botkin et al., 2003; Evans, Lalloo, Shenton, Boggis, & Howell, 2001; Lodder et al., 2002; Meijers-Heijboer et al., 2000, 2003; Scheuer et al., 2002). The low rates of mastectomy may reflect its effect on physical appearance and self-image, underlining the importance of self-construals on the uptake of risk-reduction behaviors. For example, in a study with women who had both a mastectomy and an oophorectomy, 50% of the women reported that the mastectomy had more of an impact on their sense

of womanhood because it was visible (Meijers-Heijboer et al., 2000). In contrast, the ovaries were not considered an issue of femininity if a woman had children or was post-menopausal. Both high perceived risk for cancer (Hatcher, Fallowfield, & A'Hern, 2001; Montgomery et al., 1999) and family history of cancer (Scheuer et al., 2002) have been associated with opting for preventive mastectomy, again underscoring the role of vulnerability in the decision to engage in drastic risk-reduction behaviors. Affective factors, such as low trait anxiety (Hatcher et al., 2001), high general anxiety (Lodder et al., 2002), and high cancer-related distress (Lodder et al., 2002) also have been related to the uptake of mastectomy.

Values and goals seem to play a role in the decision to have preventive mastectomy. For example, younger age (Meijers-Heijboer et al., 2000; Scheuer et al., 2002) and parenthood (Meijers-Heijboer et al., 2000) have been associated with the use of mastectomy. The trend for age seems to be related to the issue of parenthood. There is some indication that young women in the 30-40 age group, who are mothers, may be more inclined to have a mastectomy (Lodder et al., 2002). The reasons for this are unknown but it may reflect values in that a young mother may be concerned about the impact of developing breast and/or ovarian cancer on her young children.

The reasons for the large differences observed in the rates of preventive surgery among studies have not been explored systematically but it has been proposed that cultural differences (differences in values) and differences in health care systems (practical barriers) may play a role (Kaufman, DeMarco, Francini, & Schwartz, 2003). Overall, the rates for mastectomy seem to be higher in North European countries (51-64%) (Evans et al., 2001; Lodder et al., 2002; Meijers-Heijboer et al., 2000), compared to those in the US (0-15%) (Botkin et al., 2003; Lerman et al., 2000; Scheuer et al., 2002). A comparison of studies that were conducted in Europe and the US gives some indication of the reasons for the discrepancies. For example, in a Dutch study (Lodder et al., 2002), the option to speak to a surgeon was included in the genetic counseling session, whereas in a US study (Lerman et al., 2000), the women had to take the initiative to contact a surgeon. Furthermore, public and private insurers in the Netherlands cover the cost of prophylactic mastectomy, but not all insurers in the USA do that. Although more research is needed, these differences underscore the potential role that barriers in the health systems can play in the ability of women to implement risk-reduction behaviors.

Few studies have explored the impact of preventive surgery on psycho-

logical and social functioning. They have found that most women are satisfied with their decision to have a mastectomy (Frost, Schaid, Sellers, Arnold, & Woods, 2000; Stefanek, Helzlsouer, Wilcox, & Houn, 1995) and/or an oophorectomy (Meiser, Tiller, Gleeson, Andrews, Robertson, & Tucker, 2000) and report less distress after surgery (Hatcher et al., 2001). Reasons offered for their satisfaction included changes in self-construals, such as lower perceived risk for breast and ovarian cancer and expectations of higher sense of control over their body, their lives, and their future (Lodder et al., 2002; Meiser et al., 2000). This effect held despite the fact that 57% of the women were aware that the risk for cancer, although significantly reduced, had not been completely eradicated (Meiser et al., 2000). Having initiated the discussion with the physician regarding the surgery themselves and support from family are also related to high satisfaction with the decision to have a mastectomy (Borgen, Hill, Tran, van Zee, Massie, & Payne, 1998; Stefanek et al., 1995). Women who twelve months post-mastectomy experienced distress, problems with intimate relationships, and with "breast related body image," had reported these same difficulties before the surgery (Lodder et al., 2002). Montgomery et al. (1999) found that only 6% of the women who opted for mastectomy had regrets, and reasons for regret included poor cosmetic result, diminished sense of sexuality, lack of education regarding alternative screening methods or the efficacy of the procedure.

Interventions to aid decisions regarding preventive behaviors. A growing need in this area is not just to document the impact of genetic risk challenges, but to design more effective ways of preparing women to receive the genetic test results in order to maximize information processing and informed consent. One study examined the impact of a decision aid on women's intentions to have preventive surgery after feedback of test result (van Roosmalen et al., 2004). Decision aids have been found to increase the agreement between patients' values and decisions and thus are considered useful with preference-based health decisions (O'Connor et al., 1999). In this study, the decision aid consisted of a brochure and a video providing information on screening and preventive surgery and their respective physical, emotional and social consequences. The video focused on contrasting treatment options through interviews with women who had opted either for screening or for preventive surgery. Overall, women who received the decision aid seemed to be satisfied with the detailed information they were provided with and expressed greater intention to have preventive surgery compared to the women who received standard genetic counseling.

A second study examined the impact of an intervention designed to facilitate the psychological processing of the genetic test result prior to its receipt (Miller et al., 2004b). Cognitions and affects that are activated during processing health-threatening information shape intentions to take protective action, as well as their actual implementation, but individuals are often unaware of them in threatening situations (Shoda, Mischel, Miller, Diefenbach, Daly, & Engstrom, 1998). The purpose of the intervention was first to activate these cognitive-affective reactions, in a supportive environment, so that, in a second step, the women could self-assess them, that is, appraise their possible reactions to each possible test result. The first two steps allow the person to target maladaptive responses that may act as barriers to making the best decisions regarding risk-reduction and screening behaviors. By making these possible reactions accessible in the decision making process, women are helped to make informed decisions, both initially about participating in genetic testing and about their options after receipt of the genetic test result. The intervention involved structured role-play in order to facilitate the 'preliving' of the impact on the self of different genetic testing outcomes (positive, negative, uninformative), thus enhancing the processing of risk-related information.

In this study, women with a putative hereditary pattern of breast and ovarian cancer received either standard genetic counseling (plus an attention control) or enhanced genetic counseling (the intervention). One week post-result, women who received the enhanced intervention experienced less avoidant ideation than women who received standard counseling (Miller et al., 2004a). Although women who participated in the enhanced intervention, compared to the control group, had greater decisional conflict right after donating blood for genetic testing, this effect dissipated by the time they received their test result (Miller et al., 2004b). Finally, enhanced counseling participants were more likely to inquire about and to engage in preventive oophorectomy (Miller et al., 2004a). Given the recent data that preventive oophorectomy has been associated with reduced breast and ovarian cancer (Kauff et al., 2002; Scheuer et al., 2002), these results indicate that brief psychosocial interventions may be effective in helping women process and act on the information they receive. Thus, they contribute to the early adoption of risk-reduction strategies and, potentially, to lower morbidity.

Adherence to screening

Screening for ovarian cancer. Rates of screening for ovarian cancer among carriers vary from study to study, with percentages ranging from 6% to 43% for CA-125 and from 15% to 40% for TVU (Botkin et al., 2003; Lerman et al., 2000; Schwartz et al., 2003; Tinley et al., 2004). Only Scheuer et al. (2002) reported high utilization of TVU (73%) and CA-125 (68%). In this study, the recommendations regarding screening practices were twice per year, as opposed to once a year (Botkin et al., 2003) or once to twice a year in other studies (Schwartz et al., 2003). In addition, it involved a follow-up period of 15 months and a telephone call inquiring about screening practices at approximately nine months following receipt of the genetic test result, both of which could impact adherence rates. Even though the rates of utilization are sub-optimal, most studies have found that screening increases significantly among carriers, following genetic testing (Miller et al., 2004a; Scheuer et al., 2002; Schwartz et al., 2003).

As with the use of oophorectomy, adherence to screening is lower among women with indeterminate results (0-29%) and among non-carriers (5-21%), when compared to carriers (Botkin et al., 2003; Lerman et al., 2000; Schwartz et al., 2003), suggesting that perceived vulnerability (self-construal) to ovarian cancer is an important determining factor. Consistent with this interpretation, a positive personal history of cancer and a high-perceived risk for ovarian cancer have been found to predict adherence to screening recommendations (Miller et al., 2004a; Schwartz et al., 2003). Affective factors (both general and cancer-specific anxiety) are also related to higher adherence to screening for ovarian cancer (Schwartz et al., 2003).

Screening for breast cancer. Screening for breast cancer, breast self-exams and mammography, increases among carriers following receipt of the genetic test result (Botkin et al., 2003; Scheuer et al., 2002). However, a significant number of carriers do not have a mammogram, with rates of mammography in most studies ranging between 59% and 72% (Botkin et al., 2003; Lerman et al., 2000; Peshkin, Schwartz, Isaacs, Hughes, Main, & Lerman, 2002). The one study that showed a very high rate of 93% also had an 82% rate at baseline (Scheuer et al., 2002). The rates of mammography are even lower (27%) among women who receive an indeterminate result (Botkin et al., 2003). Rates for breast self-exams are 77% to 83% among carriers (Botkin et al., 2003; Scheuer et al., 2002), but 57% among women with an indeterminate result (Botkin et al., 2003). Again, these results indi-

cate that self-construals of vulnerability play an important role. Other factors positively related to adherence to screening include affective factors, in the form of cancer-specific distress (Lerman et al., 2000), and older age (Lerman et al., 2000; Peshkin et al., 2002). These factors possibly underscore the ability to regulate behavior and the role of values, as importance of health increases with age.

In conclusion, cognitive factors, particularly self-construals regarding personal vulnerability, as reflected in perceived risk and personal and family cancer history, seem to be very important in shaping risk reduction and screening behavior. Affective factors, such as worry and anxiety, also influence the uptake of preventive surgery and screening. Given that rates of uptake of preventive surgery and of adherence to screening are not optimal for carriers and for women with indeterminate results more work is needed to understand the reasons that prevent women from undergoing surgery and/or from adhering to screening. Further, interventions need to be developed that will facilitate in depth processing of genetic testing information and its consequences, so that each woman can make the best possible decision for her, given her personal values and goals.

CONCLUSIONS

This paper examined the psychological impact of genetic testing, issues related to the communication of test results to the family, and the impact of genetic testing on risk-reduction and screening behaviors. The findings reviewed clearly indicate that any negative psychological impact of a positive test result is short-lived for most women, most likely because of the reduction in uncertainty that testing allows (Croyle et al., 1997; Lerman et al., 1996; Tercyak et al., 2001). The subset of women, most likely to experience negative psychological effects of genetic testing feedback, includes women recently diagnosed with cancer, women of younger age, and women not expecting to have any negative psychological consequences from genetic testing (Dorval et al., 2000; Schwartz et al., 2002; Wood et al., 2000). Women generally communicate their positive test result, especially to spouses and adult sisters (Claes et al., 2003; Costalas et al., 2003; Hughes et al., 2001; Julian-Reynier et al., 2000). The motivation seems to be to seek instrumental and emotional support but also to provide risk information to relatives (Hughes et al., 2002). Overall, disclosure of a positive test result seems to have a beneficial effect on women participating in genetic testing,

except when the information is communicated to young children (Hughes et al., 2002; Tercyak et al., 2001).

Even though the negative psychological impact of a positive result tends to be short-lived, it is of concern that a significant number of carriers do not engage in risk-reduction and screening behaviors (Meijers-Heijboer et al., 2000; Miller et al., 2004a; Scheuer et al., 2002; Schwartz et al., 2003). Low perceived risk, low cancer-specific distress and high trait anxiety, lack of personal and family history of cancer, and high practical barriers in the health system have been implicated in the low uptake of risk-reduction and screening behaviors (Botkin et al., 2003; Hatcher et al., 2001; Lerman et al., 2000; Lodder et al., 2002; Meijers-Heijboer et al., 2000; Miller et al., 2004a; Scheuer et al., 2002; Schwartz et al., 2003; Tinley et al., 2004). Women with indeterminate results are of a particular concern because their rates of adherence to screening are quite low (Botkin et al., 2003; Miller et al., 2004a; Schwartz et al., 2003). As studies with in-depth interviews indicate, the problem may be that a percentage of them misconstrue their test result as a negative, thereby lowering their motivation to engage in increased screening (Claes, Evers-Kiebooms, Boogaerts, Decruyenaere, Denayer, & Legius, 2004; Hallowell et al., 2002). These data suggest that enhanced counseling may be necessary to effectively translate information that is not definitive into behavioral change. The results of two such studies are encouraging in that they suggest that a brief intervention can enhance the use of risk-reduction strategies and thus potentially lower unnecessary disease (Miller et al., 2004a; van Roosmalen et al., 2004).

The majority of the findings does not support a uni-dimensional model of response to high-risk status and indicate the need for a multi-factorial approach to the cognitive and emotional processing of risk feedback. Consistent with the C-SHIP model, different aspects of the self system—self-construals, values and goals, self-regulatory skills and competencies, expectancies, and affective reactions— all interact dynamically to influence behavior (Costalas et al., 2003; Hatcher et al., 2001; Scheuer et al., 2002; Schwartz et al., 2003; Tercyak et al., 2001). For example, affected women who have been diagnosed with cancer for a period of time show a different pattern than unaffected women and women recently diagnosed with cancer. It may be that the experience of living with cancer better prepares them to cope with further challenging feedback through prior solidification of perceived vulnerability and through the development of a repertoire of skills for regulating affect and behavior. Thus, when tested positive, they show better

psychological outcomes and greater uptake of risk-reduction and screening behaviors (Hallowell et al., 2002; Schwartz et al., 2002; Schwartz et al., 2003).

This review underscores a number of limitations in the existing literature, as well as directions for future research. One limitation is the lack of psychological theory to guide research in the area and to integrate the extant database. In this review, we attempted to apply an integrative cognitive-affective theory, the health information processing model (Miller et al., 1996), to conceptualize research findings in the area. A second limitation is the limited number of qualitative studies in the area. Quantitative studies have provided important information so far, in that they have identified important relationships. However, the few existing qualitative studies also have provided important complementary information. For example, qualitative studies have shown that standard measures of distress do not account for the individual's full range of emotional reactions to testing (Claes et al., 2004; Hallowell et al., 2002), and have provided important information about women's reactions to preventive mastectomy (Meiser et al., 2000). In future studies, it will be important to utilize qualitative methodologies in order to better understand a number of issues, including the complexity of the psychological reactions to genetic testing and the conditions under which post-result behavior change occurs. In addition, to date, little information is available about women who receive an uninformative test result, although this group represents a large number of women. Few studies have examined their psychological reactions to ambiguous feedback, their particular needs, and the factors that affect their decision to engage or not to engage in risk-reduction and screening behaviors.

Further, research also is warranted for the development and evaluation of interventions that might facilitate psychological adjustment, communication to the family, and behavioral change, particularly in the face of a positive or an uninformative test result. Although the management options for BRCA1/2 carriers are increasing, it is still important that decisions about follow-up be based on the individual's values and goals. Hence, interventions are needed that simultaneously enhance information processing, as well as facilitate decision-making. This is particularly important given that the two studies that involved interventions – none of which encouraged women to follow one course of action over another following the receipt of a positive test result – found that the interventions were related to increased uptake of risk-reduction behaviors and, potentially, to lower morbidity (Miller et al., 2004a; van Roosmalen et al., 2004).

Finally, the family issues that are raised by genetic testing need to be explored in greater depth. For example, it will be important to systematically study the role of the spouse in facilitating psychological adjustment to genetic testing and the uptake of risk-reduction and screening behaviors, the impact of communicating test results on adult children and siblings, and the impact of genetic testing on family planning (Smith, Ellington, Chan, Croyle, & Botkin, 2004).

The issues reviewed here are not just important in the context of *BRCA1/2* testing, but are relevant to a number of other risk contexts where the information conveyed is complex, the risk feedback is not definitive, and individuals must personally weigh their decisions about testing and subsequent management options. Psychological theory can be useful in helping to elucidate the factors that influence information processing, behavioral choices, and familial reactions over the short- and long-term. Perhaps most importantly, behavioral science approaches can be useful in guiding the design and evaluation of patient and family decision aids and supportive interventions to facilitate adaptation and functioning.

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